

OXYCONTIN: ITS USE AND ABUSE

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BEFORE THE
SUBCOMMITTEE ON
OVERSIGHT AND INVESTIGATIONS
OF THE
COMMITTEE ON ENERGY AND
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HOUSE OF REPRESENTATIVES
ONE HUNDRED SEVENTH CONGRESS
FIRST SESSION

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OXYCONTIN: ITS USE AND ABUSE

TUESDAY, AUGUST 28, 2001

HOUSE OF REPRESENTATIVES,
COMMITTEE ON ENERGY AND COMMERCE,
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS,
Bensalem, PA.

The subcommittee met, pursuant to notice, at 12:01 p.m., in Bensalem Township Public Meeting Room, 2400 Byberry Road, Bensalem, Pennsylvania, Hon. James C. Greenwood (chairman) presiding.

Members present: Representatives: Greenwood and Bass.

Staff present: Ray Shepherd, majority counsel; Nolty Theriot, legislative clerk; and Chris Knauer, minority investigator.

Mr. GREENWOOD. Good afternoon and welcome. I would like to thank Mayor DiGirolamo and thank the Bensalem Township for hosting us this afternoon and for making the municipal facilities available to us. It is appropriate that we be here today because it was in Bensalem that this issue first came to my attention.

I would also like to thank the Mayor's Executive Assistant, Ms. Barbara Barnes, for coordinating with my staff on this effort and Mr. Ralph Douglas, the Chairman of The Bensalem Cable Advisory Board, who has arranged to tape this hearing for broadcast over the township's cable system. And I believe actually it is going out live into four different townships in Bucks County.

The use and the abuse of OxyContin provides quite a dilemma for us in Congress and for the American public. For some, OxyContin is the angel of mercy; for others, it is the angel of death. To those who suffer severe chronic pain, it brings welcome relief. But for those who abuse this highly addictive drug, it can bring even greater suffering.

Today, we will hear from law enforcement officials who argue that OxyContin is quickly becoming the abuser's drug of choice, surpassing heroin and cocaine in some jurisdictions.

We will also hear from pain specialists who argue that law enforcement efforts and the reports of abuse in the media should not prevent them from obtaining this miracle drug. And I don't think anyone would disagree with that.

Let me be clear. The purpose of this hearing is not to denounce the use of OxyContin by those who benefit from its palliative effects. Far from it. This medicine has clearly alleviated immeasurably more anguish than it has induced.

Rather, today's hearing is the logical extension of this subcommittee's ongoing investigation into prescription drug abuse throughout the United States. My staff and I have met on numer-

ous occasions with the DEA, the FDA, and Purdue Pharma in order to investigate the trends of OxyContin abuse and diversion, and well as to explore potential solutions.

Sadly, prescription drug abuse is a growing national problem. According to the National Institute of Drug Abuse, as recently as 1999, more than 9 million Americans, aged 12 and older, reported that they used prescription drugs at least once that year for non-medical reasons. Nor is prescription drug abuse a new problem.

For example, from 1990 to 1998, the number of individuals initiating misuse or abuse of pain relievers increased by 181 percent, new initiates to stimulants increased by 165 percent, tranquilizers by 132 percent, and the initiates into sedative use have increased by 90 percent. It is especially disturbing to note that the most dramatic increases have been found in 12 to 17-year-olds and in 18 to 25-year-olds. There is a gentleman in the audience whose 18-year-old son perished after taking OxyContin in combination, I should say, with another drug.

Unfortunately, Bucks County, where we now sit, is in the media spotlight today because of the publicity surrounding the arrest of Dr. Paolino, who stands accused of illegally dispensing prescriptions of OxyContin to anyone with \$60. Bucks County residents purchase more OxyContin than in any other county in the State, with the exception of the large urban counties of Philadelphia and Allegheny. Nationwide, Pennsylvania ranks eighth in the per capita consumption of OxyContin.

OxyContin is a Schedule II controlled-release form of the narcotic Oxycodone. It is available in 10 milligram, 20 milligram, 40 milligram, and 80 milligram tablets. OxyContin is manufactured by Purdue Pharma and was introduced in January 1996.

Now, the 18th most prescribed drug in the United States, OxyContin had more than \$1.2 billion in sales from May of last year to May of this year. OxyContin is pure Oxycodone, with no other active ingredients, as compared to other analgesics, such as Percocet, Tylox, and Percodan. The time release formulation allows patients 8 to 12 hours of pain relief from a single dose. And there is the gentleman who introduced himself to me today who has been taking this drug for his chronic pain and is delighted that it is available to him. The drug was developed for people with severe, chronic pain. Make no mistake though, in the world of pharmaceuticals, OxyContin is to prescription drug pain relievers what jet fuel is to unleaded gasoline.

When administered correctly, OxyContin can be of enormous benefit to cancer patients and others in severe and chronic pain. One of the witnesses we will hear today, Pain Specialist Dr. Michael Levy, observes that "OxyContin is probably one of the best drugs we have seen in the past 10 years and really helps these patients."

Unfortunately, the pharmacological effects of OxyContin on those who suffer great pain are the very features that make it attractive to abusers. First, it offers reliable strength in dosage levels, and, second, it may be covered by the abuser's health insurance. Abusers have discovered that the controlled release formula of OxyContin can be easily manipulated to produce a powerful, Morphine-like high.

Law enforcement officials have criticized the drug's manufacturer of overly aggressive marketing practices and a failure to swiftly respond once the abuse of OxyContin was first reported in Maine in early in the year 2000.

In fact, on August 21, 2001, Pennsylvania Attorney General Mike Fisher accused Purdue Pharma of continuing to use overly aggressive marketing practices, such as using promotional pens and conversion charts, urging physicians, many of whom were clearly not pain specialists, to prescribe OxyContin to their patients.

Their campaign also included efforts to persuade doctors to switch patients who were receiving less addictive and less powerful painkillers to OxyContin.

Recently, Purdue Pharma took some measures to prevent abuse of its largest revenue-garnering drug by pulling its strongest 160-milligram OxyContin pills off the market in May.

They also issued tamper-proof prescription pads, which resist copying and scanning. The pads are used by 240 doctors here in Pennsylvania.

On July 25, 2001, the FDA announced that, in cooperation with Purdue Pharma, it was strengthening the warning and precautions section in the labeling of OxyContin. The changes include a "black box warning," the strongest type of warning for an FDA-approved drug, and are intended to lessen the chance that OxyContin will be prescribed inappropriately for pain of lesser severity than the approved use or for other disorders or conditions inappropriate for a Schedule II narcotic.

In addition, the company issued a "Dear Health Care Professional" letter which explains the changes in labeling and highlights the problems associated with the abuse and the diversion of OxyContin.

These actions, though commendable, also appear long overdue. According to DEA, the number of Oxycodone-related deaths has increased 400 percent since 1996, the same time period in which the annual number of prescriptions for OxyContin has risen from approximately 300,000 to almost 6 million.

Coroners in the Philadelphia region began to see death rates rise last year, as OxyContin became a more popular street drug. Oxycodone, the drug's primary ingredient, was found in 17 bodies in the city in 1999. The following year, the number rose to 41. In the first 6 months of this year, the drug was detected in 39 bodies and was the cause of death in 11 of those victims.

In its testimony today, Purdue Pharma will argue that the death figures heralded by newspapers nationwide are inaccurate and are the prime mover of the negative hype surrounding OxyContin.

The company claims that the death reports do not take into account the fact that in the vast majority of these cases, Oxycodone was detected, not OxyContin, per se. In addition, the company asserts that even in deaths where OxyContin was found, there were additional drugs present that contributed to or even caused the death of the individuals.

Law enforcement officials are skeptical of the company's claims. The chief toxicologist in the Philadelphia Medical Examiner's Office of Health care states, "Oxycodone has been in use for 80 years. The

controlled release has not been. It is that elevated dose that is killing them.”

The Delaware County coroner also argues that, “When you see 2 deaths, 3 deaths, 5 deaths, and then 17 deaths, it doesn’t take a rocket scientist to realize it is the OxyContin.”

During this field hearing, the subcommittee will hear testimony and engage in fact-finding concerning the rise of OxyContin abuse from local, State, and Federal perspectives. I look forward to hearing how DEA is working with Purdue Pharma to reduce abuse and whether Federal and State law enforcement officials are satisfied that Purdue Pharma has done all that it can to reverse this dangerous and escalating cycle of abuse.

I eagerly anticipate hearing from our local and State prosecutors in order to ascertain what tactics they have been utilizing to combat OxyContin abuse and diversion.

And, last, I am looking forward to hearing from Dr. Levy to gain a better understanding of the palliative properties of OxyContin, and from Terry Atwood who will give us a firsthand account of treatment for OxyContin abuse.

With me today, to my left, is my good friend and colleague from New Hampshire, Charlie Bass, who has flown down to be with us. He is a member of the Oversight and Investigations Subcommittee. And the gentleman is recognized for 5 minutes for an opening statement.

Mr. BASS. And I thank the chairman for recognizing me, and I also want to thank you for holding this timely and important hearing today. Prescription drug abuse is certainly a growing problem in this country, and one that prescribes, if you will, a different solution from issues involving from the abuse of nonprescription drugs. I think as a subcommittee we need to find out what the scope of the problem is, which we will do today, both from the law enforcement community, as well as from other—from our second panel.

And I think we need to address, and will address, perhaps three, perhaps more, significant issues. Firstly, what kinds of information do we now collect to monitor this problem, and do we need to have different structures and different mechanisms for developing this information so that we know what the scope of the problem is.

Second, what responsibility should be borne by what entity in determining how to deal with the rise or abuse of nonprescription drugs? What—or abuse of nonprescription drugs. What responsibility to the manufacturers or distributors or sales agents on the other side, the doctors, the pharmacies, and so forth, have in making sure that these very powerful, but important, palliative drugs, are properly controlled and not abused?

And I guess, last, I wonder what role the Federal Government and law enforcement community in general should play, if different from today, how their role should be changed, enhanced, in order to make—in order to resolve this problem, which, in my opinion, can be addressed immediately and proactively by this subcommittee, and potentially by the Congress. It is a very current issue. It is a serious issue. And I commend the chairman for bringing this issue to the attention of this subcommittee and the rest of the Congress. I yield back.

Mr. GREENWOOD. I thank the gentleman from New Hampshire. For those of you in the audience who may not be familiar with how these processes work, I thought it might help to just put it in perspective. Mr. Bass and I, as well as many other Members of Congress, serve on the Energy and Commerce Committee. It has six subcommittees, one of which is the Oversight and Investigations Subcommittee, which I currently chair and on which Mr. Bass serves.

One of our functions is to oversee those Federal agencies that deal with the pharmaceutical industries, such as—and drug issues, in general, such as the Food and Drug Administration, as well as the activities of DEA, as it relates to these kind of commercially available drugs. It is also our responsibility to oversee the pharmaceutical industry as a whole.

And so that is why we are here in a fact-finding mode, to hear from experts from around the country and from these areas, as to recommendations, what their experiences have been, what recommendations they may have for us, so that we can take that information back to Washington and see if what legislative or administrative activities that might help to resolve this problem.

We have two panels of witnesses today. The first is fundamentally a law enforcement panel, which is seated before me now. And we will hear their testimony and question them. And then we will bring a second panel consisting of representatives of Purdue Pharma, the company that makes the product, Representative Dr. Levy from Fox Chase Cancer Center, and we have an expert from the Food and Drug Administration here available to answer questions. And we will also work—have in our second panel someone who treats individuals who abuse this drug and other drugs.

I will call—I will identify the witnesses who are presently seated at the witness table. From my right to your left, we have Terrance W. Woodworth, Deputy Director of the Office of Diversion Control, for the Drug Enforcement Administration, the DEA, in Washington; Andrew E. Demarest—am I pronouncing that right—is the Senior Deputy Attorney General of the Office of Attorney General, Drug Strike Force Legal Service Section. That is under the office of Attorney General Mike Fisher.

Patrick Meehan, in the center, is the District Attorney from Delaware County and he is here to talk to us about his task force and the work he is doing in Delaware County. Christine Coulter is a Lieutenant with the Philadelphia Police Narcotics Intelligence unit; and, finally, to my left, Diane Gibbons, who is the Bucks County District Attorney, is with us today as well.

Addressing myself to the witnesses, you are aware that the committee is holding an investigative hearing. And when doing so, we have the practice of taking testimony under oath. Do any of you have objections to testifying under oath? Seeing no objections, the Chair then advises you that under the rules of the House and the rules of the committee, you are entitled to be advised by counsel. Do any of you desire to be advised by counsel during your testimony today? Seeing no responses, in that case, if you would rise and raise your right hand, I will swear you in.

[Witnesses sworn.]

Mr. GREENWOOD. So saying, you may please be seated. You are under oath. And I would ask you to each give a 5-minute summary of your testimony and we will start with Mr. Woodworth.

TESTIMONY OF TERRANCE W. WOODWORTH, DEPUTY DIRECTOR, OFFICE OF DIVERSION CONTROL, DRUG ENFORCEMENT ADMINISTRATION; ANDREW E. DEMAREST, SENIOR DEPUTY ATTORNEY GENERAL, OFFICE OF ATTORNEY GENERAL, DRUG STRIKE FORCE LEGAL SERVICE SECTION, NORRISTOWN, PENNSYLVANIA; PATRICK L. MEEHAN, DELAWARE COUNTY DISTRICT ATTORNEY, OFFICE OF THE DISTRICT ATTORNEY, DELAWARE COUNTY COURTHOUSE, MEDIA, PENNSYLVANIA; CHRISTINE COULTER, LIEUTENANT, PHILADELPHIA POLICE NARCOTICS INTELLIGENCE UNIT, PHILADELPHIA, PENNSYLVANIA; AND DIANE E. GIBBONS, BUCKS COUNTY DISTRICT ATTORNEY, OFFICE OF THE DISTRICT ATTORNEY, DOYLESTOWN, PENNSYLVANIA

Mr. WOODWORTH. Chairman Greenwood, Congressman Bass, other distinguished members and guests, I would like to thank you for the opportunity to address this subcommittee regarding OxyContin. Mr. Chairman, on behalf of Administrator Asa Hutchinson, I would like to thank the subcommittee for its interest and support in assisting the Drug Enforcement Administration with our mission of enforcing the Nation's drug laws.

The Controlled Substances Act of 1970, which assigned legal authority for the regulation of controlled substances to the DEA, established five schedules into which controlled substances are classified according to their approved medical use and abuse potential. Schedule I controlled substances have no approved medical use in the United States and have a high potential for abuse, such as heroin and LSD. Schedule II substances, including OxyContin, are approved for medical use and have the highest abuse potential among controlled substances approved for medical use.

OxyContin is made, as you said, by Purdue Pharma and is a controlled release formulation of the Schedule II narcotic, Oxycodone, used in treating chronic moderate to severe pain, when a continuous, around-the-clock analgesic is needed for an extended period of time. The controlled release formulation has an important role in the management of pain.

From the first full year of sales in 1996, the number of OxyContin prescriptions has risen 18-fold, to approximately 5.8 million prescriptions in 2000. On the other hand, another controlled release formulation manufactured by Purdue Pharma, containing Morphine, MS-Contin, saw an approximate 20-percent drop in prescriptions during that same period.

During the last 2 years, DEA has noted a dramatic increase in the illicit availability and abuse of OxyContin. As early as 1999, DEA assisted the State of Maine in the investigation of an organized ring of individuals who used forged, stolen, and altered prescriptions to divert thousands of dosage units of OxyContin to abusers. While OxyContin diversion and abuse appear to have begun more in rural areas, such as Appalachia, it now has spread to urban areas. To date, at least 14 States have experienced in-

creased abuse and diversion of OxyContin, including the State of Pennsylvania and New Hampshire.

The appeal of OxyContin for abusers, as you mentioned, is related to the larger amount of the active ingredient, Oxycodone, in relation to other narcotic products, and the ability of abusers to easily compromise the controlled release formulation. Simply crushing the tablet can negate the controlled release effect, enabling abusers to swallow or snort the drug for a powerful morphine-like high. The tablet can also be crushed, mixed with water, and injected.

In response to the escalating diversion problem, DEA has embarked upon a comprehensive action plan, focused largely on enforcement and regulatory investigations which target key points of diversion, including unscrupulous or unethical medical professionals, forged and fraudulent prescriptions, pharmacy theft, and doctor-shopping.

DEA does not intend to restrict the legitimate use of OxyContin, nor to prevent practitioners acting in the usual course of their medical practice from prescribing OxyContin for patients with legitimate medical needs. The Controlled Substance Act and DEA regulations do not attempt to define legitimate medical purpose, nor do they set standards as to what constitutes the usual course of professional practice. DEA relies upon the medical community to make these determinations.

In the past, OxyContin, as you mentioned, has been marketed and represented as having a lower abuse potential than other opioid analgesics. And one component of DEA's action plan has been to offer FDA information on OxyContin's potential for abuse to assist FDA in more accurately defining the drug's indications for medical use.

And, as you also mentioned, in July of 2001, FDA and Purdue reached an agreement regarding labeling changes and the revised package insert for OxyContin includes a prominent black box warning of the drug's abuse and diversion potential, highlighting the threat of serious injury or death resulting from its misuse. A letter calling attention to the labeling has been sent by Purdue to health care professionals throughout the country.

Other issues discussed by DEA, FDA, and Purdue Pharma include providing additional information to the medical community on the proper use of OxyContin, as well as the feasibility of reformulating OxyContin in order to prevent its—reduce its abuse potential. On August 8, the company announced the development of a reformulated version and filed for a patent.

DEA recognizes that the best means of preventing the diversion of OxyContin is to increase awareness of the proper use of this product, as well as its high potential for abuse. DEA is taking an active and measured approach to dealing with OxyContin abuse and diversion. At the same time, DEA is committed to ensuring that the valid interests of legitimate pain patients, and the health care community that serves them, are not adversely affected as a result of State, local, or Federal law enforcement efforts, media attention, or legislative or regulatory changes generated in response to the problems associated with OxyContin.

Before concluding, Mr. Chairman, I would like to, on behalf of DEA Administrator Hutchinson, and my colleagues here in the DEA Philadelphia Field Division, thank our Federal, State, and local counterparts, both law enforcement and regulatory, throughout the State of Pennsylvania, as well as the U.S. Attorney's Offices and the District Attorney's Offices around the State, all of whom we have worked with very closely over the years in combating drug abuse, diversion, and trafficking.

Chairman Greenwood, and, Congressman Bass, thank you very much for the opportunity to comment on this subject. I will be happy to answer questions at the appropriate time.

[The prepared statement of Terrance W. Woodworth follows:]

PREPARED STATEMENT OF TERRANCE W. WOODWORTH, DEPUTY DIRECTOR, OFFICE OF DIVERSION CONTROL, DRUG ENFORCEMENT ADMINISTRATION

Chairman Greenwood, other distinguished members and guests, I would like to thank you for the opportunity to address this Subcommittee regarding OxyContin®. Mr. Chairman, on behalf of Administrator Asa Hutchinson, I would like to thank the Subcommittee for its interest and support in assisting the Drug Enforcement Administration (DEA) with our mission of enforcing the nation's drug laws.

The Controlled Substances Act of 1970 (CSA) assigned legal authority for the regulation of controlled substances to the DEA. The statute charges DEA with the prevention, detection, and investigation of the diversion of controlled substances from legitimate channels, while at the same time ensuring that adequate supplies are available to meet legitimate domestic medical, scientific, and industrial needs.

The CSA established five schedules into which controlled substances are classified according to their approved medical use and abuse potential. The Food and Drug Administration (FDA) is responsible for approving drugs for medical use and for regulating the marketing of drugs by industry. Schedule I controlled substances have no approved medical use in the United States and have a high potential for abuse. Schedule II substances, including OxyContin®, are approved for medical use and have the highest abuse potential among controlled substances approved for medical use. Schedules III, IV and V include controlled substances that have a currently accepted medical use and have diminishing potential for abuse.

OxyContin® was introduced by Purdue Pharma in 1995. It is a controlled release formulation of the Schedule II narcotic, oxycodone, used in treating chronic moderate to severe pain when a continuous, around-the-clock analgesic is needed for an extended period of time. The controlled release formulation has an important role in the management of pain where dose administration should be limited to twice, rather than four to six times, per day. It is currently approved in 10, 20, 40, 80 and 160 milligram strengths.

From the first full year of sales in 1996, the number of OxyContin® prescriptions has risen 18 fold, to approximately 5.8 million prescriptions in 2000. On the other hand, another controlled release formulation manufactured by Purdue Pharma containing morphine (MS-Contin) saw an approximate 20% drop in prescriptions during that same period (from approximate sales of slightly less than 1 million prescriptions in 1996, to less than 800,000 prescriptions in 2000). Additionally, two other new products released in the mid 1990s from the same manufacturer, OxyFast and OxyLR, sold less than 100,000 and 400,000 prescriptions last year, respectively.

During the last two years, DEA has noted a dramatic increase in the illicit availability and abuse of OxyContin®. As early as 1999, DEA assisted the State of Maine in the investigation of an organized ring of individuals who used forged, stolen, washed and altered prescriptions to divert thousands of dosage units of OxyContin® to abusers. While OxyContin® diversion and abuse appears to have begun in more rural areas of the United States, particularly Appalachia, it has now spread into urban areas. To date, at least fourteen States have experienced increased abuse and diversion of OxyContin®, including the State of Pennsylvania.

The appeal of OxyContin® for abusers of controlled substances is related to the larger amounts of active ingredient, oxycodone, in relation to other narcotic products, and to the ability of abusers to easily compromise the controlled release formulation. Simply crushing the tablet can negate the controlled release effect of the drug, enabling abusers to swallow or snort the drug for a powerful morphine-like high. The tablet can also be crushed, mixed with water and injected.

In response to the escalating diversion problem, DEA has embarked upon a comprehensive action plan, focused largely on enforcement and regulatory investigations which target key points of diversion, including unscrupulous and/or unethical medical professionals, forged and fraudulent prescriptions, pharmacy theft, and doctor shopping. DEA has increased efforts to gather necessary data to better define the scope of the problem. Such data includes information regarding OxyContin® prescriptions, deaths, emergency room mentions, thefts, drug treatment program admissions, and forensic laboratory exhibits, as well as investigations, arrests and administrative actions. DEA has also written letters to each member of the National Association of Medical Examiners requesting medical examiner/autopsy, toxicology, and crime scene investigator reports on all deaths related to oxycodone in the years 2000 and 2001.

DEA does not intend to restrict legitimate use of OxyContin®, nor to prevent practitioners acting in the usual course of their medical practice from prescribing OxyContin® for patients with legitimate medical needs. The Controlled Substances Act and DEA regulations do not attempt to define “legitimate medical purpose”, nor do they set standards as to what constitutes “the usual course of professional practice”—the requisite elements of lawful prescriptions under the Controlled Substances Act and DEA regulations. DEA relies upon the medical community to make these determinations.

In the past, OxyContin® has been marketed and represented as having a lower abuse potential than other opioid analgesics. One component of DEA’s action plan has been to offer FDA information on OxyContin®’s potential for abuse relative to other opioids, to assist FDA in more accurately defining the drug’s indications for medical use. In July 2001, the FDA and Purdue Pharma reached an agreement regarding labeling changes. The revised package insert for OxyContin® contains a prominent “black box” warning of the drug’s abuse and diversion potential, highlighting the threat of serious injury or death resulting from its misuse. A letter calling attention to the labeling change is being sent by Purdue Pharma to healthcare professionals throughout the country.

Other issues discussed by DEA, FDA and Purdue Pharma include providing additional information to the medical community on the proper use of OxyContin®, as well as the feasibility of reformulating OxyContin® in order to reduce its abuse potential. On August 8, 2001, the company announced the development of a reformulated version of OxyContin®. Purdue Pharma estimates that the new formulation may be marketable in three years.

DEA has initiated meetings with the National Alliance for Model State Drug Laws, which has been the catalyst for the establishment of state prescription monitoring programs. Such programs provide a better mechanism to gather and evaluate prescription data, which is essential in responding to newly developing trends in prescription drug abuse. Existing data sources (IMS, Inc.) indicate that the five states with the lowest number of per capita OxyContin® prescriptions all have long standing prescription monitoring programs in place. These five states, beginning with the fewest per capita prescriptions for OxyContin® are California, Illinois, New York, Texas, and New Mexico. The majority of states reporting significant abuse and diversion issues are those without such programs. DEA has embarked on a number of programs to collect and monitor prescription data for controlled substances.

DEA recognizes that the best means of preventing the diversion of OxyContin® is to increase awareness of the proper use and potential abuse of the product. DEA is taking an active and measured approach to dealing with OxyContin® abuse and diversion. At the same time, DEA is committed to ensuring that the valid interests of legitimate pain patients and the health care community that serves them are not adversely affected as a result of state, local or federal enforcement efforts, media attention or legislative or regulatory changes generated in response to the problems associated with OxyContin®.

Before concluding, I would like to thank my colleagues at FDA for their cooperation in addressing this very important issue.

Finally, Mr. Chairman, I thank you and the members of this Subcommittee for the opportunity to comment on this topic. I look forward to addressing any questions that you may have at the appropriate time.

Mr. GREENWOOD. Thank you very much for your testimony. I think that the—you see these silver microphones on triangular stands. Those are the ones that are—need to be utilized for the cable television. We would now recognize—call upon Andrew Demarest, the Senior Deputy Attorney General, for the Office of Attorney General, Pennsylvania, for your testimony, sir.

TESTIMONY OF ANDREW E. DEMAREST

Mr. DEMAREST. Thank you. Good afternoon, Chairman Greenwood, and, Congressman Bass, and, members. I would like to thank the committee for giving Attorney General Fisher's office an opportunity to testify today on a problem that is exploding in Pennsylvania right now. The abuse of the brand name painkiller OxyContin is rising on a tremendous scale, placing people who are unaware of its lethal potential in danger, and placing a burden on law enforcement agencies across the State as they try to contain the distribution. I commend the committee on being so quick to shed light on this new danger. Hopefully, by giving this matter the spotlight on this matter, we can stem the tide of the deaths that abuse of this drug is causing.

A little background from what the State has seen on OxyContin—when OxyContin is prescribed, it provides effective pain management for cancer patients and others suffering with chronic pain. When properly taken, OxyContin tablet is time-released and provides the patient with up to 12 hours of pain relief. The danger arises when the time-release mechanism is bypassed. Abusers will either chew or crush a tablet. It can be snorted or mixed with water, or injected, like heroin. This puts the drug into the system all at once to deliver an intense high, much like high-grade heroin.

For example, 5 milligrams of OxyContin has the same active ingredient, Oxycodone, as one Percocet. So chewing or snorting a single 80-milligram OxyContin tablet is like taking several Percocet tablets all at once. Few abusers fully realize the enormous potency of the drug that they are taking, and, frankly, that is contributing to the deaths.

When taken by a person whose body is, in any way, intolerant to the drug, or when taken in conjunction with other depressants, like alcohol, the result will be the death of the user. The drug slows the respiratory system. The abuser will lose consciousness and breathing and will eventually die. To date, Pennsylvania has not accumulated the total number of deaths linked directly to OxyContin abuse. Remember, this is still a relatively new phenomenon, however, the medical examiner of Delaware County has reported at least 17 deaths attributable to this drug.

On the street, the drug sells for various prices, depending on the geographic location. OxyContin sells for 50 cents to \$1 per milligram. So a 40-milligram tablet, which would sell legitimately for \$4, will bring up to 10 times that amount of money on the street. So not only is the drug in demand by addicted abusers, but there is a strong profit motive in its illegal distribution, as we have seen.

The distribution scheme that is illegal in the State is seen in the following circumstances: A doctor who fraudulently prescribes OxyContin to abusers for money. A pharmacist who illegally fills an abuser's prescription, or who forges prescriptions for abusers. Abusers who steal prescription pads, and then write their own forged prescriptions. And a phenomenon we call doctor-shopping. That is individuals that go from doctor to doctor faking illness to obtain several prescriptions of the same drug. Dealers or abusers also who then burglarize pharmacies. And we have had several

armed robberies across the States of individuals breaking into pharmacies and seizing OxyContin at gun point.

In the past 2 years, the Office of Attorney General has conducted nearly 100 OxyContin abuse investigations throughout the Commonwealth. Recently, I have just approved 10 arrest warrants in the last 2 weeks, and 4 of those have been for OxyContin. The other remaining were for other prescription drugs.

Mostly notably in June, the agents of the Attorney General's Office arrested a Philadelphia man who illegally possessed over 3,000 prescription drug tablets, including a kilogram of OxyContin. This was nearly 900 tablets, with a street value of \$60 per tablet. Raymond Johnson has been charged and is under prosecution by the Philadelphia District Attorney's Office.

Additionally, there have been the other investigations that Congressman Greenwood has mentioned, including Dr. Paolino, and another one that was worked cooperatively with District Attorney Gibbons' office, Lewis Winokur, who is a Bucks County pharmacist.

In addition to these problems, our office is addressing it by working cooperatively with DEA's Diversion Unit, who has been spectacular. As far as cooperation, they have established a task force in Philadelphia. We are working directly with the Philadelphia Police Department, the State Attorney General's Office, and DEA agents.

Additionally, we are participating in regional educational opportunities for both law enforcement individuals and health care professionals. The one, which was recently held on August 21 in King of Prussia. We can alert many of the health care providers to the elaborate schemes that are used for diversion of drugs.

In addition, we have taken legislative opportunities with the State legislature. We cannot make the possession of this drug an offense, as was done with GHB, which became a Schedule I controlled substance. So we have to modulate how we attack the drug within the confines of legitimate scheduling of the drug.

One of the main undertakings that our office has done is to computerize the gathering of Schedule II prescription information. We obtain from every pharmacy in the Commonwealth, on manual form right now, a prescription printout that would show who is obtaining OxyContin across the State. We have applied for and received a grant from the Pennsylvania Commission on Crime and Delinquency and we are now computerizing that data and have been in the process of doing that for a couple of years, due to the changing pattern of technology within the pharmacy environment. We now have at least three large chain pharmacies that are doing that with us. So we will be able to target the doctor-shoppers, which are a problem. Also, there have been legislative changes.

And as far as working with the pharmacies and the doctors, we do take note that it is Pennsylvania law, according to the Superior Court, that every member of a health care team has a duty, to a limited extent, to be his brother's keeper, and we intend to make sure that they understand that obligation.

Thank you, Congressman Greenwood.

[The prepared statement of Andrew E. Demarest follows:]

PREPARED STATEMENT OF ANDREW E. DEMAREST, SENIOR DEPUTY ATTORNEY
GENERAL, PENNSYLVANIA OFFICE OF ATTORNEY GENERAL

Good afternoon Chairman Greenwood, and members of the House Committee on Energy and Commerce. I'd like to thank the Committee for giving me the opportunity to testify today on a problem that is exploding in Pennsylvania right now. The abuse of the brand name painkiller OxyContin is rising on a tremendous scale—placing people who are unaware of its lethal potential in danger, and placing a burden on law enforcement agencies across the state as they try to contain its distribution. I commend the Committee for being so quick to shed light on this new danger. Hopefully, by giving the matter the spotlight this early, we can perhaps stem the tide of deaths that abuse of this drug is causing.

Since this is such a new problem, allow me to give the Committee a little background on what OxyContin is and why its abuse has such devastating effects. OxyContin is a high potency pain killer derived from opium. When used as prescribed it provides effective pain management for cancer patients and others suffering from chronic pain. When properly taken, an OxyContin tablet is time-released and provides the patient with up to 12 hours of pain relief. The danger arises when that time release mechanism is bypassed. Abusers will either chew or crush a tablet, so that it can be snorted or mixed with water and injected—like heroin. This puts the drug into the system all at once and delivers an intense high, much like high-grade heroin. This is why OxyContin is sometimes referred to on the street as “poor man’s heroin” or “hillbilly heroin.”

For example, five milligrams of OxyContin has the same active ingredients as one Percocet—so chewing or snorting a single 80 milligram OxyContin tablet is like taking 16 Percocets all at once. Few abusers fully realize the enormous potency of the drug they are taking, and frankly, this is why many of them are dying. When taken by a person whose body is in any way intolerant to the drug, or when taken with other depressants—like alcohol—the result will likely be the death of the user. The drug slows the respiratory system. The abuser will lose consciousness and breathing will decrease until it eventually stops. To date, Pennsylvania has not accumulated the total number of deaths linked directly to OxyContin abuse—remember that this is still a relatively new phenomenon—but recently the medical examiner in Delaware County reported that 17 deaths last year [2000] were attributable to the abuse of this drug. That’s a significant number, and I believe we can expect to see similar figures throughout the southeast and across the Commonwealth.

On the street, prices for the drug vary depending on geographic location. But generally, OxyContin sells between 50 cents and \$1 per milligram. So a 40 milligram tablet which sells legitimately for \$4 will bring 10 times that amount on the street. So not only is the drug in demand by addicted abusers, there is a strong profit motive in its illegal distribution. Because OxyContin is a Schedule II prescription drug with a very legitimate value for treating chronic pain—the illegal activity of getting it into the hands of abusers is centered around pharmaceutical diversion. The illegal distribution of the drug typically involves the following criminal activity:

- A doctor who fraudulently prescribes OxyContin to abusers for money.
- A pharmacist who illegally fills an abuser’s prescription, or who forges prescriptions for abusers.
- Abusers who steal prescription pads, and then write their own forged prescriptions.
- Dealers, or abusers themselves, who burglarize pharmacies.

In the past two years, the Pennsylvania Office of Attorney General has conducted nearly 100 OxyContin abuse investigations throughout the Commonwealth. Many of these investigations have resulted in arrests, while others are still pending. Allow me to tell you about some of the recent efforts the Bureau of Narcotics Investigation has been making in this region of the State:

- In June, agents arrested a Philadelphia man who illegally possessed over 3,000 prescription drugs, including a kilogram of OxyContin. This was nearly 900 tablets, with a street value of \$60 per tablet. Raymond Johnson, of Elsinore St., Philadelphia, was charged with illegal possession of a controlled substance and possession with intent to deliver. If convicted, he faces up to 15 years in prison.
- In April, we concluded an investigation into a Bucks County pharmacist who was allegedly producing fraudulent prescriptions in order to illegally distribute OxyContin. Lewis Winokur, who practiced in a Bristol Township pharmacy, is charged with filling fake prescriptions in the names of customers he obtained from his pharmacy, and sold them to OxyContin abusers. The names of the customer’s physicians were then allegedly forged by the drug addicts. Winokur was charged with 11 counts of illegal delivery of a controlled substance by a practi-

tioner, and tampering with public records. He is facing a maximum penalty of more than 100 years in prison and more than a \$1 million in fines.

- In March, our BNI agents and Bucks County law enforcement officers arrested Dr. Richard Paolino, who practiced in Bensalem. Our investigation alleges that Paolino's practice amounted to a revolving door for OxyContin junkies. The confidential informant, who worked with our agents, went to Paolino's office every month to get OxyContin and Xanax without ever being examined. We allege that it was standing room only in Dr. Paolino's waiting room, and most of the patients were gaunt, with dilated eyes. Some "patients" showed obvious signs of withdrawal. Dr. Paolino allegedly only accepted cash for office visits—\$66 for the first visit, \$59 thereafter. Paolino was allegedly handing out so many prescriptions that our office was originally alerted to the problem by a Philadelphia pharmacist who was being confronted with so many Paolino Oxy prescriptions that he eventually stopped filling them.

In addition to dedicating agents and resources to investigating specific instances of abuse, the Bureau of Narcotics Investigation will be operating regional educational programs for both law enforcement agencies and health care professionals. Since the abuse of OxyContin is such a new phenomenon, most local police forces lack the experience to properly target the problem in their communities. Health care professionals, such as pharmacists, also need to be educated to the potential this painkiller has to be diverted into a lethal street drug. The Office of Attorney General's experience in dealing with OxyContin abuse needs to be disseminated throughout the Commonwealth. For although the problem is particularly bad in the southeast, it will quickly spread.

The first conference—which was held on August 21st in King of Prussia—is designed to give local law enforcement agencies training in dealing with this new epidemic of drug abuse. We can share our office's experience in attacking the problem. We can identify the abuser population that is likely to possess the drug. We can alert them to the often elaborate schemes that are used to divert this scheduled drug out of the hospitals and pharmacies and onto the street where it kills. For example, the Bucks County case I mentioned earlier involved a medical professional—a licensed pharmacist—manipulating the records of his workplace in order to duplicate legitimate prescriptions and sell them to drug addicts. This is not a run-of-the-mill street drug distribution ring with which local investigators are familiar. Medical professionals, as well, need to be aware of ways this dangerous drug can fall into the wrong hands.

These are the actions that our office has taken and will continue to take in response to this new drug epidemic: targeted enforcement of the current drug laws and education of local law enforcement agencies. But you, as members of Congress, are wondering what you can do to assist law enforcement in fighting the problem. OxyContin presents a somewhat unique problem because it is a legitimate drug that—when properly prescribed and taken—serves as a valuable tool in treating chronic pain. We cannot simply make its possession an offense, as the Pennsylvania General Assembly did in 1999 when it made GHB a Schedule I controlled substance. Any attempt to deal with this problem statutorily must be aimed at the diversion of the drug from its intended pharmaceutical use to its abuse as an illicit street drug. Our office has offered the following legislative recommendations to the Pennsylvania General Assembly:

- The theft of a prescription blank or a prescription pad should be a distinct offense punishable as a third degree felony. Right now, the theft of a prescription blank is graded only on the value of the paper—a low misdemeanor. But the potential street value of the prescription drugs that can be illegally obtained with just one pad of blanks can be thousands—perhaps hundreds of thousands—of dollars. That is the value on which the offense should be graded. Each of those little slips of paper must be viewed as a significant source of revenue for the OxyContin dealer, and the possible death for the addict who doesn't know the danger of the drug he or she is taking.
- The outright theft of a prescription drug should be a felony offense under the Controlled Substances Act. Currently, the Controlled Substances Act only prohibits the obtaining of prescription drugs through fraud or forgery. The simple theft of these drugs is a Title 18 offense, graded on their actual, legitimate commercial value—which is relatively low. The penalty for stealing these drugs should reflect their potential both in street value and in harm to the user.
- The practice of "doctor shopping" should be a distinct offense under the Controlled Substances Act. Very often, illicit prescriptions for drugs like OxyContin are obtained by one individual who visits doctor after doctor complaining of phantom symptoms. The prescriptions are then filled and the dealer is in business. This practice should be recognized and punished for the crime that it is.

Again, I'd like to thank Chairman Greenwood for inviting me here today to testify on this new wave of drug abuse that threatens our communities. I believe that directing both the public's and Congress's attention to the abuse of OxyContin at this stage in the trend will help to minimize the damage it causes.

I would be happy to answer any questions the members of the Committee may have.

Mr. GREENWOOD. I thank you very much for your testimony. We now turn to Patrick Meehan, the Delaware County District Attorney.

TESTIMONY OF PATRICK L. MEEHAN

Mr. MEEHAN. Good morning, Mr. Chairman, or good afternoon, Mr. Chairman, and good afternoon, Congressman Bass. And I want to thank you for giving me this opportunity to speak on behalf of law enforcement, but also just to speak as one who is a prosecutor, but a community leader. And I think that we have looked at this issue in Delaware County as one which is not just exclusively a law enforcement issue, but also one that is really a public health issue. And we have taken a collaborative approach to that problem, and I know that is something, in communications with your staff, that you wanted me to articulate more on in the 5 minutes that you have scheduled. So rather than be redundant with some of the information, I would like to focus a little bit on that.

I have some opening observations. I think you couldn't be more on point with your identification of the paradox here with this drug. It is—and I have gotten phone calls from people who are using this with legitimate prescriptions who are in severe pain and talk about what a tremendous difference it has made to their lives. But we are also dealing with people who now are abusing it or addicted to it. We have crimes that grow out of that addiction.

And, as I will demonstrate, we believe and we have seen verifiable proof of increased deaths in Delaware County as a result of it. So that paradox exists that, you know, those who legitimately use OxyContin fear that the recent controversy will mean tighter restrictions on the drugs, but abusers will go to great lengths, legal or illegal, to gain that powerful drug.

You know, we see it come in, in a variety of different ways. And my greatest concern, as a prosecutor, is its movement into what we call the recreational use or the rave scene, so to speak. And there is reasons a drug like this can begin to ingratiate itself into that scene. I think that like Ketamine, GHB, and Ecstasy, what we have are some characteristics. One, it is a manufactured drug. And there is this perception out there that because it is not produced illicitly, like heroin or cocaine, that somehow there is some level of safety. And so those who are abusers are looking for the drug itself.

But we have a significant number of kids that are experimenting. And they are using not just alcohol, but a whole bevy of drugs. And this has found its way into what we call the club-drug scene. And I think it is particularly dangerous because of our concerns of what it can do. Because it is not a drug that is taken intravenously, the kids don't have the same concern about AIDS or hepatitis contamination. I think that it has a salability—you know, the kids, where when it is marketed out there in the street, we call it the Madison Avenue side of the drugs—you know, there are OC's or Oxy's out

there and the Ecstasy. These kind of manufactured drugs sound good to the kids and, as a result, they are not as threatening.

And, of course, one of the things that needs to be understood, and I think it is accurate, it is not a drug that is operating solely and exclusively. While there may be some who are using it for the ability to be responsive to their addiction, what we are seeing is that the drug is often used in combinations with other drugs, even addicts may be using it in combination with alcohol or other kinds of prescription drugs.

My biggest concern, as a prosecutor, and someone in public health, is the potential that it is truly a gateway drug to more serious abuse, and specifically heroin. And when we begin to deal with somebody who is addicted to heroin, we have significant issues, both from a public health perspective and a law enforcement perspective because of the associated crime that often is associated with the necessity, to find the money to pay for it.

And what is unique about OxyContin is the fact that it sort of builds in something that heroin and cocaine don't. The market for heroin and cocaine, the illicit market, you know, has increasing steps, from distributors on down, and the profit margins are incremental.

With Oxycodone, somebody—or, OxyContin, somebody who can get a \$4 tablet legitimately prescribed, or get it through diversion or doctor-shopping, or all the things we have talked about, you know, gets a \$40 markup out on the street. So in addition to feeding the addiction, there is a natural attraction to go after this particular drug because it helps to perpetuate the opportunity to feed the addiction.

You are going to hear a lot from law enforcement about the issues of diversion, pharmacy robberies, other kinds of things, new laws that ought to be established. And I didn't want to necessarily go there, except to articulate one particular concern. And I was away in Boston just this last week, and one of the things that happened there is it is not just pharmacies up there. They had a nursing home that was raided at gun point late in the evening. And we have to be aware that this drug is not just available only in pharmacies. And I think we have got a particularly vulnerable population. And I have a concern that this is the kind of crime that could be repeated in other areas of the country.

When we approached this again, we looked at it, as I said, I have got a responsibility to the criminal justice side, and we are very proactive, along with all my colleagues, looking at increased enforcement whenever we see a problem.

But when we began to see a problem, we have a history over the last 4 years in Delaware County of identifying community-wide problems. We have worked on the issue of school safety and crisis response. We went to the issue of identification of at-risk kids. The third year, we looked at the issue of youth suicide in schools. And the fourth year, in consultation with the group that I regularly meet with once a month, which consists of our county medical examiner, my chief probation officer, the head of our Department of Public Health, the head of my county school system, and myself, we try to identify issues we think that are of community concern and collaboratively look at a way to approach it.

And it was in that context that our medical examiner, Rick Hellman, who is a tremendously distinguished person in his own right and looks at his responsibility to be more than just, you know, dealing with death after the fact, but in a community health perspective—and you will see to my right what we have experienced in Delaware County. And I will just very briefly explain one small bit of it.

What we have done over the course of time is to track a 10-year history of Oxycodone abuse in Delaware County. And the medical examiner went through historically of all the records from the period of 1991 through the year 2001. Now, we weren't talking OxyContin in many of those earlier years because, of course, it was not a manufactured drug at that point in time. But we did have Percodan and Percocet, you know, the 5-milligram tablet. And what you can see is, in our county of about 500,000 people, you saw an average of about 3, 4, 5 deaths a year in which Oxycodone was one of the agents that attributed—that was attributed to overdose deaths.

Mr. GREENWOOD. If I can interrupt you. If you take your seat and describe the chart, I think they will be able to hear you on the television, and otherwise, they won't be able to. I am afraid that is a technical problem we have.

Mr. MEEHAN. I am sorry, Mr. Chairman. And I can do that from here just as easily. But as you look over the charts, again, what I wanted to identify for you is, as the medical examiner went through those statistics over a 10-year period, what you begin to see, almost commensurate with the introduction of OxyContin, and regularly into commerce, is the critical year of 2000, when we had 18 deaths. So the dramatic spike of about 4 a year to 18 deaths. And as of the first 5½ months of the year 2001, we have had five associated with it at this point in time.

We took an approach to this then that was community-wide and it led to each of us trying to define a way that we could influence the problem. We have worked with each of our health care providers so that we are trying to have our county medical society and our pharmacy association do two things. One, they are communicating down the lines with specific information to both pharmacists and to doctors in our region, giving them vital information about this problem. They are also trying to track information on how it is being used in Delaware County.

We are working with our treatment providers to identify whether we are getting an increase in this kind of drug abuse. And I can tell you anecdotally, we have seen about a 20-percent increase in self-reported abuse by people who are seeking treatment. And we are working with our school system and others in a comprehensive effort to make this a critical educational objective this year so that throughout our school system, throughout our law enforcement community, what we want to try to do is educate people about the potential for abuse.

And, again, the critical segment that we are trying to get to is that user population that might be fooled into thinking that there is not danger associated with recreational use of the drug. The abuser population is more complicated. And we are also talking

with our folks about treatment modalities, to have somebody step down to—you know, once they have had that issue.

So I wanted to show the statistics which verify the concern and then articulate at least what is a community-wide approach that we have tried to take to the problem. Thank you, Mr. Chairman. [The prepared statement of Patrick L. Meehan follows:]

PREPARED STATEMENT OF PATRICK L. MEEHAN, DELAWARE COUNTY DISTRICT ATTORNEY

Chairman Greenwood, members of the committee, ladies and gentlemen. Thank you for the opportunity to be here with you today to talk about a serious issue that affects both our public health and the fight against crime. That problem is the growing abuse of a legal prescription drug, Oxycontin.

The drug Oxycontin has presented public officials at all levels of government with a unique problem. One the one hand, this drug, when used properly, as prescribed by a caring physician, can be a life-enhancing solution to the severe pain suffered by people afflicted with debilitating injuries and diseases. On the other hand, when this powerful drug is abused, by being crushed or chewed and ingested, it can kill. This powerful drug presents such a clear paradox that a Web site devoted to the controversy surrounding it begs the simple question: Oxycontin—Savior or Killer?

As a local prosecutor, my first and foremost concern about this drug is its potential to become an attractive drug of choice for recreational users and in particular for the young people who populate the "Rave Culture." Prosecutors have already seen the drugs Ecstasy, GHB, and Ketamine become popular with recreational users because the abusers have deceiving themselves into thinking that they are not as harmful as illegal drugs such as cocaine and heroin. This deception occurs for a number of reasons: (1) Because these drugs are manufactured, not produced illicitly, abusers have a false sense of security in the drug's safety. (2) Because these drugs are not taken intravenously, abusers feels safe from AIDS or hepatitis contamination. (3) Prescription or chemical drugs come with what I call a "Madison Avenue-type" appeal; their scientific-sounding names raise the sense of excitement for the user. And lastly (4) these drugs are readily available. They are, after all, sold legally at the neighborhood drug store to anyone with a prescription.

Oxycontin abuse by recreational users is particularly disturbing because the drug can become a "Gateway" drug to other narcotics, such as cocaine and heroin. Whenever a recreational user begins narcotic drug use, the potential for addiction is great. The recreational user who began narcotics with Ecstasy or Oxycontin may need to continue to get his high, but often finds the legal supply inadequate or unavailable, sometimes because of price. Oxycontin is an expensive drug, selling on the street for \$0.50 to \$1.00 per milligram. Prescription use calls for 2 tablets a day—each tablet, through a timed release, providing pain relief over a 12-hour period. Abusers will crush or chew the tablet to get the instant high, making the drug potentially lethal, but also requiring more tablets for abusers to stay high. Because Oxycontin may cost \$40-\$80 per tablet on the street, addicts may find it cheaper to buy cocaine or especially heroin, which unfortunately are easily available in Southeastern Pennsylvania.

The abuse of prescription drugs has created issues for prosecutors that may require changes in the law. First, the most important function of law enforcement in the fight against prescription drug abuse is to combat the sale or "diversion" of the drug by a new breed of drug dealers. These drug dealers are not of the usual "street—corner variety". Increasingly, we are seeing doctors and pharmacists engage in these "diversion" schemes by selling sale prescription drugs to abusers. The Bucks County case of Dr. Richard Paolino is a perfect example of the professional fraud that we know exists when you have a product like Oxycontin, which sells on the street for \$40 to \$80 per tablet and is capable of producing such an addictive high that it is commonly called "the Poor Man's Heroin."

As you will hear today from other speakers, Pennsylvania's Attorney General Michael Fischer is working with the General Assembly on legislative proposals to give law enforcement new tools to combat the diversion of prescription drugs. First, he is seeking to increase the criminal penalties for the theft of either prescription "scripts" or for the drugs themselves. Second, he is seeking the creation of a new crime to stop the practice of "doctor shopping" to acquire prescriptions. Attorney General Fischer has also been working in cooperation with the federal Drug Enforcement Agency (DEA) to create an electronic pharmacist reporting system here in Pennsylvania. These systems, in place in states like Kentucky, have allowed law enforcement to more closely monitor and catch pharmacists and doctors who partici-

pate in drug diversion schemes. I support their efforts and I hope we will see legislative action in Harrisburg on these proposals this fall.

But we know that solutions to the problem of the abuse of prescription drugs like Oxycontin are not just matter of criminal law. This is a community problem, requiring collaborative efforts between government institutions, and in combination with civic and professional organizations. That is the approach we have taken in my county, Delaware County, which I am proud to share with you today.

In Delaware County, the problem of Oxycontin abuse was first brought to our attention by the work of our Medical Examiner Dr. Frederick Hellman. As you can see from the accompanying charts (Chart 1), Dr. Hellman has documented 18 deaths in our county in the year 2000 where at the time of death the decedent had Oxycodone in their system, usually in combinations with other drugs that the decedent had been abusing. These 18 deaths represented an explosive increase in Oxycodone abuse in our county. We had never before had more than 5 such deaths in one year since the introduction of the drug Oxycontin into the marketplace in 1996. Yet in just the month of April of 2000 alone, (Chart 2) there were 6 Oxycodone related deaths in the county. We have attributed this increase to the growing popularity of Oxycontin as a drug of choice for abusers on the east coast. These numbers are proof that Oxycontin abuse, which first began in southern and midwestern states, has now moved east to the metropolitan areas of the Mid-Atlantic States.

When Dr. Hellman brought his findings to the attention of myself and members of the Delaware County Council, we decided to address the problem by using a collaborative interdepartmental approach. We focused on three goals: (1) education, (2) prevention, and (3) prosecution. For us in Delaware County, this was not a departure from standard practice but another application of our working county governmental paradigm to a new challenge.

Increasingly, we in county government find ourselves challenged by community problems that have no easy answer. Under Pennsylvania law, it is the primary responsibility of county government to provide for systems of law enforcement and behavioral human services for our communities. We have found, in Delaware County, that the problems we deal with in law enforcement generally have a human service aspect that must be addressed. We have come then, over the last several years, to find that the most efficient and productive way to do our jobs for our constituents is to work together.

We first created this collaborative paradigm in our efforts to combat school violence. In the spring of 1997 I brought together school administrator, teachers, local police, and behavioral service providers to work together to begin to identify issues of school safety in our county. In November of 1998, this working group hosted our first Safe Schools Summit. The result of that summit and the one that followed was the development of a "Delaware County model" of training for first responders to incidents of critical school violence. That model, developed through real school violence simulation exercises, has been distributed across the country in a videotape format by the National Tactical Officers Association (NTOA), who have endorsed this training model. This year we devoted our third Safe Schools Summit to the often overlooked issue of teen suicide and the need to identify and combat what is the third leading cause of death for American teenagers.

We are now applying what we have learned by working together on safe schools, to the problem of Oxycontin abuse. In July, I held a press briefing along with Dr. Hellman to begin the educational campaign about Oxycontin. Our County Council later dedicated a public meeting to the issue and has since required all county agencies to work together to identify abusers who come into our offices for behavioral treatment. County Council also has produced a public informational flier on the dangers of Oxycontin. To further our goal of prevention through public education, we are getting that flier to our county agencies and to such groups as the Delaware County Medical Society.

The next, and perhaps most vital step in our county campaign against Oxycontin abuse, is the educational effort we will undertake this fall in our schools to raise the awareness of our young people to of the danger of this drug's abuse. As we all know, many students unfortunately begin experimenting with recreational drugs at an age when they possess a misguided sense of invincibility about such dangerous things. It is for their protection that we will be devoting our next Safe Schools Summit to the overlooked issue of prescription drug abuse.

My hope is that our Delaware County collaborative approach to combating oxycontin abuse will be a model for other counties to follow, as they face this issue important public health issue, and I thank the members of this committee for their time and attention today.

Mr. GREENWOOD. Thank you, Mr. Meehan. Thank you for your testimony and for being with us. Next, we will hear from Christine Coulter, Lieutenant, Philadelphia Police Narcotics Intelligence Unit. Thank you for being with us, and the floor is yours.

TESTIMONY OF CHRISTINE COULTER

Ms. COULTER. Good afternoon, Chairman Greenwood, Mr. Bass, members of the committee. I am honored to be here to speak to you on behalf of the Philadelphia Police Department regarding the abuse of OxyContin in the communities we serve. I must admit that prior to the fall of 2000, I knew very little about OxyContin. In the months to follow, there was a concerted effort made by my colleagues and myself to learn all that we could so we could better combat this emerging problem.

I will leave the medical testimony for the medical professionals regarding the legitimate use of OxyContin. I am here today to testify solely about the drug's abuse in Philadelphia and our surrounding counties and the law enforcement efforts to combat this problem.

The effects of this abuse has been devastating to many families and communities in our area. The increase in deaths in Philadelphia where there was a presence of Oxycodone in the body is quite alarming. The Office of the Medical Examiner reported 17 cases in 1999, 41 cases in 2000, and, in June of 2001, there are already 39 reported cases. If this trend continues, it will likely result in the death toll from abuse doubling in 2 consecutive years.

Although Oxycodone is present in other substances of abuse, and there were indications that other pills and alcohol were also contributing factors, we would be remiss in not reacting to the increase with a sense of urgency.

The abuse of OxyContin in Philadelphia is a rather recent development. Beginning last year, we began to experience some problems that our fellow law enforcement officers in surrounding areas have dealt with for quite some time. The migration to the city and surrounding suburbs happened quickly, necessitating the development of a strategy that would stem the tide of OxyContin abuse. We had to quickly examine the areas of diversion so we could implement a suitable plan to combat abuse.

An analysis was done and it was determined that there were three major diversions present in our city. The first is the outright theft of the product, or prescription pads, from legitimate patients, pharmacies, or practitioners. These thefts were committed by relatives, employees, and, in some instances, robbers and burglars.

Second, individuals without legitimate medical necessity can obtain OxyContin by reporting made-up symptoms of pain to unwary, uneducated, or disinterested practitioners. This method is a low-risk alternative for pill diverters, since prescriptions is issued in the person's name, often at a low-cost as well, since medical insurances normally cover most of the cost of the pill. This also engenders the practice of doctor-shopping, going from one doctor to another, giving the same complaint, and getting the medications repeatedly described. It is not uncommon to do so using multiple names and prescription plans and having the prescriptions filled at multiple pharmacies to camouflage this fraudulent practice.

The third and often largest diversion method are pill-mill operations, where corrupt doctors or pharmacists conspire with pill traffickers to write or fill fraudulent prescriptions for ghost patients and then selling the drug on the street at up to 100 percent profit. There is also the presence of insurance fraud in this diversion method, as health plans, both private and governmental, are billed by providers for falsely reported office treatments and prescriptions dispensed.

High volume operations, such as pill-mills, lend themselves to tracking by audits of physician records and pharmacy orders of commonly abused controlled substances such as OxyContin Drug diversion agents from both the Drug Enforcement Administration and the Pennsylvania Attorney General's Office, Bureau of Narcotics Investigations and Drug Control, have the ability to administratively inspect and analyze such records. There is currently a tremendous amount of cooperation with these agencies, which enables us to build strong cases, while eliminating duplication of effort and wasted resources.

Local law enforcement, however, does not presently have the authority to administratively subpoena prescription records. Enabling local police officers to analyze these records will encourage a more proactive investigation of drug diversion conspirators on the local level. Coupled with aggressive prosecution and enhanced sentencing of licensed health care professionals engaged in prescription drug diversion schemes, it may also discourage such corrupt practices. There is also a need for legislation to make all pharmaceutical thefts a felony, factoring in the street value of the drug into the equation.

There was also a great need to train our officers, as well as educate health care providers and the public alike. Training bulletins were prepared for our officers and seminars were attended to gain insight to the problems associated with OxyContin abuse. In an effort to better educate the public, the police department incorporated OxyContin, as well as other prescription drugs of abuse, into its Heroin Education and Dangerous Substance Use Prevention, or HEADS-UP program, which educates middle to high-school age children, as well as parents and community groups, in an hour-long presentation by police, recovering addicts, and surviving family members of overdose victims. Since April of 2001, this program was presented to over 11,500 people.

There are currently significant investigations being conducted by the Philadelphia Police Department and by joint task forces with local, State, and Federal agents that deal with OxyContin diversion. This is, however, a problem that we cannot arrest our way out of. It will require a balanced blend of prevention, treatment, and enforcement. It will also require legislative changes to act as strong deterrents. There have already been too many deaths. The attention that this committee will hopefully bring to this problem is just the beginning of the concerted effort needed to prevent future escalation. I thank you for your attention, and I will be available to answer any follow-up questions you may have.

[The prepared statement of Christine Coulter follows:]

PREPARED STATEMENT OF CHRISTINE COULTER, PHILADELPHIA POLICE DEPARTMENT

Good Afternoon, Mr. Chairman, honorable members of the Committee. I am Christine Coulter of the Philadelphia Police Department's Narcotics Bureau. I am assigned to the Narcotics Intelligence Squad. I am honored to be here today to speak to you on behalf of the Philadelphia Police Department regarding the abuse of Oxycontin in the communities we serve. I must admit that prior to the fall of 2000 I knew very little about Oxycontin.

In the months to follow there was a concerted effort made by my colleagues and myself to learn all that we could so we could better combat this emerging problem.

I will leave the medical testimony for the medical professionals regarding the legitimate use of Oxycontin. I am here today to testify solely about the drug's abuse in Philadelphia and our surrounding counties, and law enforcement efforts to combat this problem. The effects of this abuse has been devastating to many families and communities in our area.

The increase in deaths in Philadelphia where there was a presence of Oxycodone in the body is quite alarming. The Office of the Medical Examiner reported 17 cases in 1999, 41 cases in 2000, and as of June 30th, 2001 there were already 39 reported cases. This will likely result in the death toll from abuse of this drug doubling in two consecutive years. Although Oxycodone is present in other substances of abuse, and there were indications that other pills and alcohol were also contributing factors, we would be remiss to not react to the increase with a sense of urgency.

The abuse of Oxycontin in Philadelphia is a rather recent development. Beginning last year we began to experience some of the problems that our fellow law enforcement officers in the surrounding areas have dealt with for quite some time. The migration to the city and surrounding suburbs happened quickly, necessitating the development of a strategy that would stem the tide of Oxycontin abuse. We had to quickly examine the areas of diversion so we could implement a suitable plan to combat abuse.

An analysis was done and it was determined that there were three major methods of diversion present in our city. The first is the outright theft of the products, or prescription pads, from legitimate patients, pharmacies, or practitioners, by relatives, employees, or others, including burglars and robbers.

Second, individuals without legitimate medical necessity can obtain Oxycontin by reporting made-up symptoms of pain to an unwary, uneducated, or disinterested practitioner. This method is a low-risk alternative for the pill diverter, since the prescription is issued in the person's name, and often low cost as well, since medical insurance normally covers most of the cost of the pill. This also engenders the practice of "Doctor-Shopping", going from one doctor to another, giving the same complaint, and getting the medications repeatedly prescribed. It is not uncommon to do so using multiple names and prescription plans, and having prescriptions filled at multiple pharmacies to camouflage the fraudulent practice.

The third and often the largest diversion method are "pill-mill" operations, where-by corrupt doctors and/or pharmacists conspire with pill traffickers to write or fill fraudulent prescriptions for "ghost" patients, and then selling the drugs on the street at up to 100% profit. There is also the presence of insurance fraud in this diversion method, as health plans both private and governmental are billed by providers for falsely reported office treatments and prescriptions dispensed.

High volume operations such as "pill-mills" lend themselves to tracking by audits of physician records and pharmacy orders of commonly abused controlled substances such as Oxycontin. Drug Diversion Agents of both the Drug Enforcement Administration and the Pennsylvania Attorney General's Office, Bureau of Narcotics Investigation and Drug Control have the ability to administratively inspect and analyze such records. There is currently a tremendous amount of cooperation with these agencies, which enable us to build strong cases, while eliminating duplication of efforts and wasted resources. Local law enforcement, however, do not presently have the authority to administratively subpoena prescription records. Enabling local police officers to analyze these records will encourage a more proactive investigation of drug diversion conspirators on the local level. Coupled with aggressive prosecution and enhanced sentencing of licensed health care professionals engaged in prescription drug diversion schemes, it may also discourage such corrupt practices. There is also a need for legislation to make all pharmaceutical thefts a felony, factoring in the street value of the drug into the equation.

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and Dangerous Substance Use prevention (or HEADS-UP) program, which educates middle to high school age children, as well as parent and community groups, in hour long presentations by police, recovering addicts, and surviving family members of overdose victims. Since April of 2001 this program was presented to over 11,500 people.

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Mr. GREENWOOD. Thank you very much for your testimony that you bring us today, as well. And our final witness on this panel is our Bucks County District Attorney, Diane Gibbons. Thank you for joining us.

Ms. GIBBONS. Thank you, Mr. Greenwood, and, Mr. Bass.

Mr. GREENWOOD. The floor is yours.

TESTIMONY OF DIANE E. GIBBONS

Ms. GIBBONS. Bucks County, Pennsylvania, like so many communities across this State and this country, has experienced a virtual explosion of the abuse of the prescription pain reliever OxyContin. As District Attorney of Bucks County, I have witnessed firsthand the sudden influx of OxyContin and the corresponding devastating effects this drug has had—has begun to have on our community.

As has already been said, OxyContin is intended to be a pain reliever for cancer patients and others suffering from long-term debilitating pain. Its potency and time-release design have made OxyContin more effective and desirable to these patients. The popularity of the drug for legitimate purposes is understandable and even compelling. But it is this same potency that has become attractive to drug abusers. This drug has become the drug of choice among an increasing number of drug addicts who are drawn to its instantaneous heroin-like high. Drug abusers will risk death to experience this high the drug produces.

Since January of 2000, Bucks County has experienced 14 overdose deaths involving OxyContin. The drug is extremely addictive and will, as with all addictive substances, create new drug addicts if overly or improperly prescribed. In addition to its popularity among drug abusers, the high mark-up on the streets makes OxyContin attractive to drug traffickers as well. The retail cost of a 100-tablet prescription bottle containing 40-milligram tablets of OxyContin, is \$400. The pills in that same prescription bottle sold on the street, are worth \$4,000.

The abuse of OxyContin has brought with it a new kind of drug dealer to our neighborhoods. This drug is not manufactured in home laboratories like methamphetamine. It is not smuggled across our borders like heroin or cocaine. This drug is produced by a legitimate pharmaceutical company. It is prescribed by medical doctors. It is distributed by professional pharmacists. These are the professionals that we, as lay people, have come to trust and believe in. Recently, the citizens of Buck County have experienced two sep-

arate incidents that have left the foundation of this trust badly shaken.

In March of this year, acting in a cooperative effort with the Attorney General, DEA, and other local law enforcement authorities, we arrested a physician operating out of Bensalem Township, Bucks County, on drug dealing, forgery, practicing without a license charges. This "physician" is charged with having written 1,200 prescriptions for OxyContin over a 5-month period. We recently charged the same physician with 1,392 counts of insurance fraud for fraudulently submitting claims for reimbursement from Medicare and Blue Cross in the amount of \$173,892.10.

Despite the fact that this doctor's license to practice medicine had both expired and was suspended, large numbers of people were able to obtain OxyContin by merely asking for a prescription. One prescription bottle with this doctor's name on it was found in the possession of an overdose victim in Philadelphia. Following his arrest—and this—I refer to Dr. Paolino—the OxyContin overdoses in that area of Philadelphia immediately ceased. Despite the expired and suspended status of his license, Dr. Paolino was able to receive reimbursement from both Medicare and Blue Cross in the amount of \$107,702.

In April of 2001, in another joint investigation, a pharmacist was arrested and charged with forging prescriptions, the majority of which were for OxyContin. Again, hundreds of these illegal prescriptions were generated, thereby allowing this illegal and deadly drug to make its way to our streets.

A third and very frightening incident occurred on August 9 of 2001, in Bristol Township, Bucks County. On that date, a man, armed with a knife, entered a pharmacy, held a knife to that pharmacist and demanded that the pharmacist turn over three bottles of OxyContin. Fortunately, the pharmacist was able to flee the store without injury while the armed robber collected the drugs that he sought.

Too often, as a society, we think that drug abuse and drug addiction is someone else's problem, not ours. Those of us here and those of us in law enforcement understand that nothing could be further from the truth. These three incidents, which occurred at Bucks County over the last 6 months, indicate the kind of criminal activity OxyContin has created, not only here, but on a national level as well. But they do not demonstrate the whole picture.

Drug addicts, by definition, must become criminals to support their habit. The tremendous costs to support the addiction leads to a host of crimes—theft, forgery, credit card fraud, robbery, burglary, and murder. Drug dealers engage in a host of crimes beyond the sale of controlled substances in order to protect their drug territory.

The people of Bucks County and across the Nation will suffer the impact of the abuse of this drug, not only as victims of crimes, but in the cost of insurance and the cost of retail goods and the added expense to the criminal justice system for arrest, investigation, prosecution, and treatment.

The reaction of law enforcement must be swift and strong in identifying, arresting, prosecuting, and convicting those involved in the distribution and use of this dangerous drug. My office and

every other law enforcement agency in Bucks County and in the Commonwealth of Pennsylvania, are committed to utilize every resource available to combat this killer. But the criminal justice system alone cannot solve this problem. It will require the cooperative effort of the pharmaceutical industry, medical practitioners, pharmacists, the insurance industry, and government to fully regulate and control the distribution of this extremely dangerous drug.

In conclusion, I want to say this—law enforcement has worked very closely to stem the tide of this problem in Bucks County. All the officers, the law enforcement officers here today, worked with me on all the cases that I mentioned. What has not occurred is that the medical profession, the prescription—the pharmacists, the insurance companies have not worked together to share information. Dr. Paolino was able to engage in his criminal conduct for 5 months without detection because we do not share information about prescriptions, what doctors are writing prescriptions, and how many prescriptions those doctors are writing. So I think there is an answer to this problem. Thank you very much.

[The prepared statement of Diane E. Gibbons follows:]

PREPARED STATEMENT OF DIANE E. GIBBONS, DISTRICT ATTORNEY, BUCKS COUNTY

Bucks County, Pennsylvania, like so many communities throughout the country has experienced a virtual explosion of the diversion and abuse of the prescription pain reliever OxyContin. As District Attorney of Bucks County, I have witnessed first hand the sudden influx of OxyContin and the corresponding devastating effects that this drug has begun to have on our community.

OxyContin is intended to relieve the pain of cancer patients and others suffering from long-term debilitating pain. Its potency and time-release design make OxyContin more effective and desirable to these patients. The popularity of the drug for legitimate purposes is understandable and even compelling. But it is this same potency that has become attractive to drug abusers. This drug has become the drug of choice among an increasing number of drug addicts who are drawn to the instantaneous “heroin-like” high the pill produces. Drug abusers are willing to risk death to experience the high the drug produces. Since January of 2000, Bucks County has experienced fourteen overdose deaths involving OxyContin in combination with other controlled substances. This drug is an extremely addictive drug and will, as with all addictive substances, create new drug addicts if overly or improperly prescribed. In addition to its popularity among drug-abusers, the high mark-up on the streets makes OxyContin attractive to drug traffickers. The retail cost of a 100-tablet prescription bottle of 40-milligram tablets of OxyContin is \$400. The pills in that same prescription bottle, sold on the streets, are worth \$4,000.

The abuse of OxyContin has also brought with it a new kind of drug dealer to our neighborhoods. This drug is not manufactured in home laboratories like Methamphetamine or smuggled across our borders like Heroin and Cocaine. This drug is produced by a legitimate pharmaceutical company, prescribed by medical doctors and distributed by professional pharmacists. These are the professionals that we, as lay people, have come to trust and believe in. Recently, the citizens of Bucks County have experienced two separate incidents that have left the foundations of this trust badly shaken.

In March of this year, acting in a cooperative effort with the Attorney General of Pennsylvania, Mike Fisher, we arrested a physician operating out of Bensalem Township, Bucks County, on drug dealing, forgery and practicing without a license charges. This “physician” is charged with having written over 1,200 prescriptions for OxyContin over a five-month period. We recently charged the same “physician” with 1392 counts of insurance fraud for fraudulently submitting claims for reimbursement from Medicare and Blue Cross in the amount of \$173,892.10. Despite the fact that this doctor’s license to practice medicine had both expired and been suspended, large numbers of people were able to obtain OxyContin by merely asking for a prescription. One prescription bottle with this doctor’s name on it was found in the possession of an overdose victim in Philadelphia. Following his arrest, the OxyContin overdoses in that area of Philadelphia immediately ceased. Despite the expired and

suspended status of his license, this doctor was able to receive reimbursement from both Medicare and Blue Cross in the amount of \$107,702.

In April of 2001, in another joint investigation with the Office of the Attorney General, a pharmacist was arrested and charged with forging prescriptions the majority of which were for OxyContin. Again, hundreds of these illegal prescriptions were generated thereby allowing these illegal and deadly drugs to make their way to the streets.

A third and very frightening incident occurred on August 9, 2001 in Bristol Township, Bucks County. On that date, a man armed with a knife, entered a pharmacy, pointed the knife at the pharmacist's throat and demanded that he turn over three bottles of OxyContin. Fortunately, the pharmacist was able to flee the store without injury while the armed robber collected the drugs he sought.

Too often, as a society, we think of drug abuse and addiction as somebody else's problem, not ours. Those of us in law enforcement know that nothing could be further from the truth. These three incidents, which occurred in Bucks County over the last six months, indicate the kind of criminal activity OxyContin has created not only here but also on a national level. But they do not demonstrate the whole picture. Drug addicts by definition must become criminals to support their habit. The tremendous cost to support the addiction leads to a host of crimes—theft, forgery, credit card fraud, robbery, burglary and murder. Drug dealers engage in a host of crime beyond the sale of controlled substances as they try to protect their territory. The people of Bucks County and across the nation will suffer the impact of the abuse of this drug not only as victims of crime but in the cost of insurance and retail goods and the added expense to the criminal justice system for investigation, prosecution, incarceration and treatment.

The reaction of law enforcement must be swift and strong in identifying, arresting, prosecuting and convicting those involved in the distribution and use of this dangerous drug. My office and every law enforcement agency in Bucks County are committed to utilize whatever resources are available to combat this killer. But the criminal justice system alone cannot solve this problem. It will require the cooperative effort of the pharmaceutical industry, medical practitioners, pharmacists, the insurance industry and government to fully regulate and control the distribution of this extremely dangerous drug.

Mr. GREENWOOD. And thank you very much for your testimony. We appreciate it. The Chair now recognizes himself for 10 minutes for the purpose of questioning the witnesses. And let me start, if I might, with Mr. Woodworth. According to the DEA, since its introduction in 1996, OxyContin prescriptions have increased by 1,800 percent to 6 million in the year 2000. How do you account for this incredible growth of sales in only 4 years, and do you think that Purdue Pharma's marketing techniques are a factor in this dramatic rise?

Mr. WOODWORTH. Thank you, Mr. Chairman. The product was new. So I think a significant factor is the newness of the product. It's a very valuable, legitimate medication, used in the treatment of pain. And I am sure that that is a significant factor that contributed to the rapid increase in sales from about 360,000 to, as you say, just under 6 million prescriptions.

I do think that the marketing played a significant role. And coupled with the marketing, was the message. And the message was that this substance was less abusable than other opioids. And, as defined by the Controlled Substances Act, a Schedule II substance, which all your stronger narcotics are in Schedule II, they have a high potential for abuse, severe physical and psychological dependence characteristics.

Mr. GREENWOOD. Let me interrupt you for a second. Would you elaborate on the message that you said that Purdue Pharma communicated to the physicians that this was a less abusable drug? What was the argument there?

Mr. WOODWORTH. In fact, in their label, which has now being changed, I believe the language was delayed absorption is believed to reduce the abuse liability, and messages like that. We also have indicators from—about Purdue salesman indicating that the substance has less abuse and should not be a Schedule II controlled substance. And that message is inaccurate because this is a Schedule II and it meets the definitions by law. I think that was a contributing factor.

Mr. GREENWOOD. Also according to the DEA, emergency department reports involving Oxycodone, the generic active ingredient, had increased 200 percent since 1996. In addition, coroner reports involving Oxycodone have increased 400 percent since 1996. Do you know how much of this is attributable to OxyContin?

Mr. WOODWORTH. No, sir. We don't. The time period that we utilized was the same time period that the product has been on the market, from 1996 to 1999. And I can give you some 2000 figures for emergency room mentions. The 200 percent was inaccurate. It increased from 3,190 mentions in 1996 to 6,429 in 1999. It is a doubling. The ME's was from 51 to 267, 400-percent increase.

The emergency department mentions, for a number of years, from 1988 to 1996, have run fairly stable, about 1,000 mentions per quarter. And in 1996, you see them shoot up. And then in 2000, there were 10,800 emergency mentions. So this is—

Mr. GREENWOOD. Re-read those numbers again. Between 1988 and 1996—and define what you mean by a mention in an emergency department.

Mr. WOODWORTH. Actually, an episode is the correct term. This is the Drug Abuse Warning Network that is managed by the Department of Health and Human Services, Substance Abuse and Mental Health Services Administration. And an emergency department episode is largely self-reported, where someone goes to the emergency room and they are asked the drug that they are on. The mentions from 1988 through 1996 were roughly 1,000 per quarter during that time period. And in 1996, as I mentioned, they went to 3,190. And then they increased in 1999 to 6,429. And in 2000, they are at 10,825, I believe.

Mr. GREENWOOD. So a tenfold increase in the number of times that Oxycodone—

Mr. WOODWORTH. The base substance, Oxycodone.

Mr. GREENWOOD. [continuing] Oxycodone is referenced in a visit to. It comes up in a conversation with someone brought to the emergency room. In other words, what drugs did you take before you were brought here semiconscious or unconscious and so forth. So we have these numbers of deaths, but we are seeing a tenfold increase. And obviously a lot of people abuse this drug, overdose from this drug, and that doesn't result in their death. They are coming to the emergency room in various conditions, a tenfold increase in seeing the presence of this drug associated with emergency room visits. Is that right?

Mr. WOODWORTH. Emergency room, emergency department episodes. Yes, sir. On the deaths, in the DAWN system, it was just 51 in 191996, and then 267 in 1999. DEA is writing to each medical examiner throughout the country to obtain the autopsy and toxicology reports and the crime scene investigation in order to see

if we can more accurately determine whether the percentage of Oxycodone deaths that were attributable to OxyContin.

Mr. GREENWOOD. You have been quoted in the press as being highly critical of Purdue Pharma's slow response to the abuse of OxyContin. In particular, when asked if the company should have investigated adding antagonists to OxyContin to prevent abuse, you stated, "It should have dawned on them sooner." What should the company have done sooner to prevent all this abuse?

Mr. WOODWORTH. Well, I have been involved in this business for 30 years, working with the pharmaceutical industry here in the United States for that entire time. Purdue is an outstanding company and they have been in business making pain medications for a long time. They possess some of the best scientific and pharmaceutical knowledge and expertise that exists in the world. I just find it very difficult to believe that that situation wasn't addressed earlier.

Mr. GREENWOOD. Can you elaborate on that? What might they have done? My question to you is what should they have done sooner? Is there any question in your mind that they knew that they had a problem early on, prior to the year 2000? For instance, that they knew that this drug was being abused in unprecedented levels? That this drug was causing death? That this drug was on the streets? Any question in your mind that the company should have known that, certainly, 2 years ago?

Mr. WOODWORTH. There certainly was no question in my mind, and I believe that that would be the same case for Purdue Pharma.

Mr. GREENWOOD. That they were aware of it. How long have you personally been aware of the fact that this drug was having an alarming rate of abuse?

Mr. WOODWORTH. Well, it is difficult to define alarming. Now, DEA had a case in 1996, soon after it came on the market, in Richmond, Virginia. Another three or so cases in 1998. In 1999, a half dozen, including some here in Pennsylvania. And then 37 in 2000, and now we are up to 168 cases. And that is just DEA at the Federal level. It doesn't include our State and local counterparts.

Mr. GREENWOOD. Let me turn to this side of the table to District Attorney Gibbons. You have characterized distributors of OxyContin as "a new kind of drug dealer." And while you cite the recent arrests of a doctor and a pharmacist, are these abuses by such professionals isolated incidences or do you have reason to believe that this is more common?

Ms. GIBBONS. It is not going to be isolated. I mean, this is a drug that is not manufactured by lay people. It is not made in local labs. It is not grown. It is not imported. For this drug to be abused, it must come from a legitimate source. It must come from the manufacturer or from a doctor or from a pharmacist. The mere fact that we have seen this amount of this drug on the street, means that that is, in fact, happening. And it is not one doctor in Bensalem, Bucks County, but the number of pills that are causing these numbers of deaths on—in the market. Of course, there is going to be prescription fraud, but, as we have seen, pharmacists have conspired with that. There will be robberies to commit these crimes. Bucks County has not seen so much a forcible crimes to obtain the

pills, so much as a greedy distribution of these pills on the street for money.

Mr. GREENWOOD. Let me yield 10 minutes to the gentleman from New Hampshire, Mr. Bass.

Mr. BASS. Thank you very much, Mr. Chairman. Ms. Gibbons, I note that you mentioned in your testimony that this drug has the potential to have a devastating impact, and I agree with you, also tempered by the fact that it has provided, as you well understand, tremendous relief to perhaps hopefully many more people. You also mentioned that—an example that there was a physician that wrote 1,200 prescriptions. Now, that is not really the fault of the drug company necessarily directly.

In your opinion, what action do you think should have been taken and should be taken, or a corrective action to be taken to prevent this sort of thing from happening again, and starting, perhaps, with the manufacturer and going down through, in this case, the State of Pennsylvania and into the Federal level?

Ms. GIBBONS. We—you are absolutely correct. We—my mother passed away of cancer. I would have loved to have this kind of pain pill to make her last days better for her. But given the fact that it is being abused, and we know it is being abused, and this company, as the chairman says, has got \$1.2 billion in sales. There is things we can do and I think they have to contribute to it. And one of those things is to monitor the distribution of those pills.

It is hard for me to track down a meth lab because I don't know where the meth lab is. Is it in the Poconos? Is it in Upper Bucks County? But I know where this drug is coming from. And given the fact that the source of this drug comes from one sole source, it should be easy, very easy, to track the distribution of that drug. And that requires sharing of information among the different organizations, the medical profession, the drug company, the pharmacies, having access to DEA's information, and, as Christine said, my ability to go into a pharmacy and do some kind of audit.

One of the questions I could not answer when I announced the insurance fraud arrest of Paolino and the drug dealing arrest, was average citizens can see this. It is common sense. A guy came up to me and said, wait a minute. If the guy doesn't have a license to practice law—or to practice medicine, I mean, how come pharmacies are still filling his prescriptions? And how come the insurance companies are still paying his claims? And it is a simple matter of fact that we don't share information.

Law enforcement shares information. I worked with every one of these law enforcement authorities to arrest both the pharmacist and the medical doctor. But the license status of this doctor was never shared with the people who were filling his prescriptions and the people who were paying his bills.

And I think if we set up a system, given the fact that we know the source of the drug—you know, where is the drug going? What doctors are prescribing what amounts? Is that doctor properly licensed? You know, is the pharmacy properly accounting for its 500 pills or 5,000 pills, or whatever it has in its local stores? Law enforcement could have been keyed into this particular problem months before we actually were able to find out that this doctor and this pharmacy were doing this.

Mr. BASS. Mr. Demarest, you mentioned in your testimony that—if I could paraphrase, that you seem to be able to get just about all the information you really need. On the other hand, there isn't a conflict, but Ms. Coulter mentioned that she didn't have—it wasn't as easy to get—I am not sure—and maybe it was Ms. Gibbons that mentioned this. And I am just curious to know, do you have access to the records and information that you need in order to adequately monitor the situation with respect to the abuse of this drug or any other prescription drug subject to abuse?

Mr. DEMAREST. Congressman, the monitoring system of drugs depends from State to State because there is the Federal aspect and then there is the State aspect. The Federal aspect is covered by ARCOS, which is an electronic computer system that is run by DEA. DEA covers the sales of narcotics and other Schedule II drugs to pharmaceutical chains from wholesalers, or to doctors that are dispensing the drugs.

In the State of Pennsylvania, we have a system where we are able to monitor only Schedule II drugs. That would be—one of them which would be Oxycodone or OxyContin. So we would have a manual data base with all 3,500 pharmacies in the Commonwealth reporting this every month, how many Schedule II prescriptions they have. There are over 2 million of those types of prescriptions issued a year. And with Pennsylvania senior population increasing, we are seeing an increase, too, in general narcotic type of prescriptions. So those prescriptions are now manually capped.

Other States monitor both the Schedule IIIs and the Schedule IVs. Schedule III is also a problem. That is Vicodin or Hydrocodone. That, before OxyContin hit the front page, was really a major problem. So that drug in Pennsylvania is not monitored by law enforcement. So, to answer your question, we should have OxyContin prescriptions monitored. We are now developing a computer system that will get that data directly from the pharmaceutical chains. But all 3,500 pharmaceutical outlets have different technologies and to allow to dump that data to the State. But we are making substantial headway.

Mr. BASS. Ms. Coulter, you stated that the Bureau of Narcotics Investigations and Drug Control has the ability to inspect and analyze physician records and the pharmacy orders. I am wondering if these inspections are routine or are they triggered by certain factors? And is it done in such a manner as to protect patient privacy?

Ms. COULTER. Right. See, the local law enforcement does not have that right right now. The State does, but local cannot. And I just feel that with that right, it would prohibit someone who may get involved in corrupt activities from even getting involved. If they knew that—there are so many pharmacies. I mean, there is one on every other corner in Philadelphia. But if they knew that the local law enforcement agents could come in and check them, it may just be another check in the system to keep them from being involved in that.

I realize and recognize the patient's rights, and I think that is very important. But from—to just look at the scope of what is being prescribed, if you have specific pharmacists that are not necessarily next to Fox Chase Cancer Center, or somewhere where there should be a higher increase, it would be nice to know that just to

ensure that, you know, we are protecting the community that surrounds that area.

Mr. BASS. Well, I guess, Mr. Chairman, if I could, I have just three more questions for Mr. Demarest. You represent the Attorney General in the State of Pennsylvania. And it is—is it your feeling that Purdue Pharma has taken appropriate action in response to increased reports and evidence of growing abuse of their product?

Mr. DEMAREST. Congressman, I think there are a few things that they did well. And one of those was to distribute the tamper-proof prescription pads, which I think was well-taken. Some States took that measure on their own prior to that problem, but Purdue has made that available to other States.

I guess the real issue comes down to the marketing of the actual product. And, as you are aware, there was, for example, pens given out comparing dosage qualities—quantities to certain other drugs that are a substantially lower schedule. One, Propoxyphene or Darvocet, a Schedule IV—the pen that Purdue gave out compares it to OxyContin.

Mr. BASS. What is a pen? Do you mean the thing you—

Mr. DEMAREST. Here it is. It is an actual—

Mr. BASS. Okay.

Mr. DEMAREST. Here it is. It would—

Mr. BASS. All right. It is an advertising—it is advertising.

Mr. DEMAREST. Can you show him?

Mr. BASS. Okay.

Mr. DEMAREST. I have never—I have only looked at kind of photos.

Mr. WOODWORTH. It has OxyContin on blue on the side of it. It has a little scroll that you pull out and it says how to convert patients to OxyContin. And on the flip side it tells you the other substances that you can use to do that, including Darvocet, which is a Schedule IV, Tylenol with Codeine. And so that is the message that we are talking about.

Mr. DEMAREST. And that is a concern because the drugs, while they are both painkillers, to use a generic term, they are different in how they have been ranked, as far as abuse potential goes.

Mr. BASS. Well, are you suggesting that advertising for Schedule II drugs be regulated differently?

Mr. DEMAREST. I think it—

Mr. BASS. I mean, that is all that is, is an advertisement. Right?

Mr. DEMAREST. That is correct. And you still have the corresponding duty of the physician when they write that prescription for the patient. But, as we know, there is a reason why drug companies market, because it impacts on sales.

Mr. BASS. Sure.

Mr. DEMAREST. So there is a symbiotic relationship between the marketing the product reaching the streets.

Mr. BASS. I have no further questions, Mr. Chairman.

Mr. GREENWOOD. Thank you. The Chair recognizes himself for an additional 10 minutes. I direct a question to you, Mr. Meehan. From your experience in Delaware County, can you give this committee a sense of the profile of the abusers in your county, both those that have died as a result of their abuse, and to the extent that you are aware of others who had close calls and ended up in

the emergency rooms and so forth? I am trying to get a sense whether these are hardened long-time drug abusers who are shifting from a more expensive drug or a more criminalized drug or a hard-to-get drug, and have found OxyContin to be just the next phase in their chronic abuse of drugs, as opposed to young people. Again, I reference a gentleman I spoke with just before the hearing, whose family's 18-year-old son got in the unfortunate practice of doing pill popping with friends not realizing, as the gentleman said to me, one drug plus one drug doesn't equal two. And, in this case, one plus OxyContin equals ten, in terms of the dangers. What can you tell us about the profile of the people you see abusing this drug in your county?

Mr. MEEHAN. I think that there is a dichotomy and I think you have accurately identified it. Among the 26 deaths or the 25 deaths that we analyzed in the most recent years, predominantly we saw people who had a history of drug abuse. And, as I indicated before, those who died often died not only with Oxycodone as one of the ingredients, but some other kind of abused drug as being part of it.

And I have often focused on the fact that that is an abuser population who may have actually found this as an alternative to other kinds of abused drugs. And it may, at the outset, be something that is an alternative to heroin. For an abuser, it has that rush-like quality that is something that is consistent with heroin. And, as a result, there is a defined abuser population.

My concern is the extent to which we are generally seeing it move beyond the abuser population and into what we call the recreational drug area—the rave scene, the club scene. And we know it. My detectives are out on the street and they see it. And the kids are now carrying it in the clubs. And it is not just GHB and Ketamine and Ecstasy. It is now, in addition, OxyContin. And the biggest concern we have is the generally addictive nature of the drug.

Mr. GREENWOOD. Let me turn back to Mr. Woodworth for a second, from the DEA. My understanding is that there is a private data base, and you help me understand this, that records the prescriptions per physician for these Schedule II drugs. And that data base—I know that the company will have them here shortly. The company has a data base. They know every physician in the country that is writing prescriptions for this OxyContin and they can—they have a data base that they get from—well, I understand it is a private source that—and then they can arrange that data to start to show who are the physicians that are prescribing the most and rank them.

To what extent does DEA have access to that kind of information?

Mr. WOODWORTH. As you mentioned, Mr. Chairman, it is a private company, IMS Health. And DEA purchases prescription information from this company. And we do so on a fairly regular basis from several of their different data bases, the National Prescription Audit and the National Therapeutic Index, on a fairly regular basis to do that type—

Mr. GREENWOOD. And what do you do with—I know here in Bucks County we had Dr. Paolino, who is as bad an actor as you

can find. The guy has gone bankrupt. He has got sexual harassment cases going. He has lost his license. He is practicing without a license. And he essentially ends up selling prescriptions at whatever it was, \$69 or \$60 a pop to walk in the doors. When DEA, when your people came in, he had a standing room only office of zombies trying to get their hands on the next prescription. Now, does DEA—or should DEA have, from this data base, been able to see the Dr. Paolinos of the world who were doing 1,200 scripts in, what was it, a month, 1,200 prescriptions in—over 5 months for this particular addictive substance?

Mr. WOODWORTH. No, sir. The information in that data base is not provided by name, so we would have no idea of the physician.

Mr. GREENWOOD. So then what does it say? What does this information tell you, just the total gross number of prescriptions?

Mr. WOODWORTH. We rate them—rank them by the number of prescriptions per State.

Mr. GREENWOOD. Per State.

Mr. WOODWORTH. So that is what we would be able to do for Pennsylvania, provide the State and local authorities with the number of prescriptions.

Mr. GREENWOOD. Okay. But that does not come down to the physician level.

Mr. WOODWORTH. No, sir. Under the Controlled Substances Act, that responsibility was specifically relegated to the individual States to address the retail level, doctors, and pharmacies. That information would be provided not in the numeric detail to our State and local counterparts. It would be a profile of the trends.

Mr. GREENWOOD. Okay. Let me ask, perhaps, a final question for Ms. Gibbons. In the 14 overdose cases in Bucks County since January of 2000. These are 14 overdose cases with OxyContin.

Ms. GIBBONS. Involving—in each case, there were other substances involved.

Mr. GREENWOOD. And that is what I want to get a sense of. Can you shed a little light on what the profile is in Bucks County, if you will, or at least to what extent there were other drugs present, alcohol present in the decedent's body?

Ms. GIBBONS. Well, we—I don't know the specifics in terms of what the—what was determined at the autopsy. I do know in each case it was not just OxyContin. There were other things involved. It is difficult to come up with a profile in Bucks County. You know, I have been in the DA's office in Bucks for 18 years. I was not even aware of OxyContin until 2000. And I think that the same—the medical examiner would say the same thing. So we don't have enough experience to know if this is—to determine any kind of trends.

I can say, you know, as Pat did, that we have made arrests of sales of OxyContin out of bars. So it will hit the general street population and it will hit the recreational user. There is no doubt about it. Percocet did. OxyContin will go the same way.

Mr. GREENWOOD. Maybe I will ask Ms. Coulter the same kind of question in terms of—that I have asked Mr. Meehan and now Ms. Gibbons. In terms of the profile of the people that you see using the drug, in terms of—I think we have heard a consistent theme here, that the fear is that this is a drug that may be working its

way from the hardened, chronic drug abuser who finds that the next cheapest, easily accessible, profitable, if you will, drug to use, to the kids who are experimenting and may find themselves taking the fatal dose, and what they expect is just a recreational kind of a lark.

Mr. COULTER. That is pretty much what we are seeing in Philadelphia. We are seeing recreational use within the 15 to 25-year range. We are seeing it on other levels as well. But it is the most disturbing because I really feel that the people who are experimenting really feel it is safe because it is a pharmaceutical.

Like when we debrief prisoners or people who are arrested for either possession or selling, there isn't that sense that it is heroin or it is something that is dangerous, because it is made by people who are doctors. It is not a danger, like street-level drugs, that you don't know what you are getting in the heroin pack. That they really feel they are getting a safe product. And the street corner sales are absent all of the necessary warnings that are provided when you buy it and use it legitimately. And—

Mr. GREENWOOD. Do these kids seem to have any concept that others who have come before them are dying? In other words, I suspect that these 15, 16, 17, and 18-year-old kids are not picking up the Philadelphia Inquirer every morning or watching the nightly news and following these events. Are they surprised to find out how dangerous these drugs are?

Ms. COULTER. You know, they are not surprised how dangerous they are, but I think they are still at that age where they really feel they are invincible, that it will only happen to somebody else and that this isn't going to happen to me because I am not going to take the highest milligram or I am not going to mix it with two drugs; perhaps I will only mix it with one. But just alcohol alone, or the pill itself, you know, used improperly, has that same deadly affect. But it seems very hard to reach that age.

And that is why we have incorporated it into our HEADS-UP program where we are starting at the middle school level where they don't have that invincible nature yet, that they still will learn what it is and what could happen if you did it just once. And that is what we are trying to communicate, that a lot of our fatalities weren't life-long abusers, that they are people who have tried it once or twice, or mixed it with another drug or alcohol and it had deadly results.

Mr. GREENWOOD. Okay. Thank you. Mr. Bass, any other questions at this time?

Mr. BASS. No, Mr. Chairman. I just wanted to advise, as you well know, I am going to leave in about an hour. I hope that our next Panel of witnesses, because they do represent a different part of this whole issue, will be able to give this subcommittee a good idea as to exactly what OxyContin is and how it compares to Schedule I drugs, which apparently—which have no medical use. And what we have gotten into with this line of questioning here is really the issue of a Schedule II drug which has good medical applicability getting into the category, one way or another, of Schedule I. And how these people who come about it from a different—not from the law enforcement side, propose that, you know,

the State and Federal authorities deal with the problem. And I yield back.

Mr. GREENWOOD. Let me just offer that the panelists, if there is any of you who feel that there is a point that you haven't made that you want to get across, something that this committee should know—have we asked you all the right questions? Are there other comments or statements you felt you need to—to help us put on the record?

Ms. GIBBONS. I just want—I would like to make one statement because this is in Bucks County, and I know it is going to hit my media and I am worried about this. I understand that most of the deaths occurred because they were in combination with other drugs. But I don't want the message to go out to other kids that, you know, the kids—hey, I can take it as long as I don't take it with something else. I am going to be safe. Because that is not the case. They could die with the pill alone. They could die with alcohol. And while our experience has been other drugs were involved, I don't want to send the message that if other drugs aren't involved, they are okay.

Mr. GREENWOOD. And that is an excellent point, and I thank you for making it. And I thank each of the witnesses for being with us today and for your testimony and you are now excused. Thank you.

We will now call forward our next panel of witnesses. And they are Michael Friedman, Executive Vice President and Chief Operating Officer of Purdue Pharma.

Okay. If we can resume order here. Our next panel consists of Michael Friedman, Executive Vice President and Chief Operating Officer of Purdue Pharma. We would call him forward. As well as Michael Levy, Dr. Michael Levy, M.D., and Ph.D, Vice Chairman of Medical Oncology, Director of Supportive Oncology, and Director of the Pain Management Center at the Fox Chase Cancer Center; Terry Atwood, Registered Nurse; and Dr. John Jenkins, Director of the Office of Drug Evaluation, The Center for Drug Evaluation and Research Food and Drug Administration.

And I would ask the audience to please take your seats again and desist from conversations, please, so that we can have the attention of our witnesses. Thank you, each of you, for being with us. You are aware that this committee is holding an investigative hearing. And when we do so, we have had the practice of taking testimony under oath. Do any of you have objections to testifying under oath? Seeing no objections, the Chair then advises you that under the rules of the House and the rules of the committee, you are entitled to be advised by counsel. Do you desire to be advised by counsel during your testimony today?

Mr. FRIEDMAN. Yes, Mr. Chairman. I am advised by Mr. Howard Udell and Dr. Paul Goldenheim. It is my intention to defer to my colleagues when you or the Congressman Bass have questions relating to their areas of responsibility.

Mr. GREENWOOD. In that case, when I swear the witnesses in, your counsel who will be advising you will be asked to take the oath as well.

Mr. FRIEDMAN. Thank you, Mr. Chairman.

Mr. GREENWOOD. Anyone else who wished to be advised by counsel? All right. In that case, if you would please rise and raise your

right hand, I will swear you in, and that includes any counsel who will be advising.

[Witnesses sworn.]

Mr. GREENWOOD. Okay. In that case, you are under oath. And ask you to please be seated. And we will begin by calling Michael Friedman from Purdue Pharma for his testimony.

TESTIMONY OF MICHAEL FRIEDMAN, EXECUTIVE VICE PRESIDENT, CHIEF OPERATING OFFICER, PURDUE PHARMA, L.P., ACCOMPANIED BY HOWARD UDELL, EXECUTIVE VICE PRESIDENT AND GENERAL COUNSEL, AND PAUL D. GOLDENHEIM, SENIOR PHYSICIAN; MICHAEL H. LEVY, VICE CHAIRMAN MEDICAL ONCOLOGY, DIRECTOR OF SUPPORTIVE ONCOLOGY, DIRECTOR, PAIN MANAGEMENT CENTER, FOX CHASE CANCER CENTER; THERESA ATWOOD; JOHN JENKINS, DIRECTOR, OFFICE OF DRUG EVALUATION II, CENTER FOR DRUG EVALUATION AND RESEARCH, FOOD AND DRUG ADMINISTRATION

Mr. FRIEDMAN. Thank you, Mr. Chairman. My name is Michael Friedman and I am the Executive Vice President and the Chief Operating Officer of Purdue Pharma, the distributor of OxyContin tablets and other medications. My responsibilities at Purdue include the direct oversight and management of sales, marketing, human resources, licensing, and business development.

With me today, and available to answer the committee's questions, are Mr. Howard R. Udell, our Executive Vice President and General Counsel, and Dr. Paul D. Goldenheim, the Senior Physician at Purdue. Dr. Goldenheim is responsible for all research, development, and both regulatory and medical affairs at our company. Mr. Udell has the primary responsibility for the company's U.S. legal affairs.

Before I begin my brief remarks, I ask to place on the record my entire opening statement for the hearing record, along with two accompanying annexes to my remarks, which are in the committee's possession and available at this hearing.

Mr. GREENWOOD. Without objection, those documents will be entered into the formal record.

Mr. FRIEDMAN. Thank you, Mr. Chairman. On behalf of Purdue Pharma, L.P., the distributor of OxyContin tablets, thank you for taking the time to hold this hearing. We are more distressed than anyone at this hearing that our product, which is providing so much relief to so many people, is being abused. The availability of OxyContin is critical for millions of patients who are suffering from moderate to severe pain where a continuous around-the-clock analgesic is needed for an extended period of time.

Unfortunately for those patients, concern generated by the abuse of OxyContin has mushroomed to the point that in some locations, some patients are asking their doctors to switch them to less effective medicines, some doctors are refusing to renew patients' prescriptions for OxyContin, and some pharmacists are no longer willing to carry OxyContin for their patients. Purdue receives alarming reports every day from such physicians and patients. For these patients in pain, this hearing is timely and important.

Today's hearing should focus on a significant question of public health policy—how to address the problems of abuse and diversion which accompany the sale of controlled prescription drugs like OxyContin without restricting its availability to meet the needs of doctors and patients for the effective management of pain? This question is neither new nor unique to OxyContin. It has existed as long as opioid analgesics have been available. It is a critical question, and we are confident that Purdue has devoted more resources and efforts than any pharmaceutical company in attempting to answer this question. Purdue has provided, and continues to provide, extensive assistance to the law enforcement communities and medical communities in preventing and policing the abuse of OxyContin.

While all of the voices in this debate are important, we must be especially careful to listen to the voices of patients who, without drugs like OxyContin, would be left suffering from their untreated or inadequately treated pain. Purdue frequently hears stories of how OxyContin has enabled people to return to their families and to productive lives after suffering disabling pain. We urge you to hear directly from some of these patients at future meetings. They are not addicts. They are not criminals. They are people who, because of cancer, sickle cell anemia, severe back injuries, or some other physical insult or disease, have had their lives taken away from them by unrelenting pain.

Amidst all the publicity and controversy, a few facts do stand out. First, the problem of chronic pain in this country is enormous and it is expensive. According to organizations like the American Pain Foundation, an estimated 50 million Americans suffer from chronic pain, with a cost approximating \$100 billion attributable to lost workdays, excessive or unnecessary hospitalizations, unnecessary surgical procedures, inappropriate medication, and patient-incurred expenses from self-treatment. Even more important than all of this, is that these are people in pain who are suffering.

Second, chronic pain has been historically undertreated. In this decade, for the first time, public and medical opinion has swung decisively in favor of active treatment of pain, in part, based on the proven effectiveness of opioid therapy in treating pain and the startling improvement in quality of life such therapy can offer to patients.

In 1994, the Department of Health and Human Services issued new guidelines encouraging the use of opioids in the treatment of cancer pain. In February 1999, the Veterans Administration added pain as a fifth vital sign, along with pulse, temperature, respiration, and blood pressure, that should be checked regularly as major indicators of health.

Congress, itself, has aggressively worked to help the cause of recognizing pain as a vital part of modern medical treatment. On October 28, 2000, Public Law 106-386 was enacted declaring the decade commencing on January 1, 2001, to be the Decade of Pain Control and Research. Bills currently pending in both the House and Senate, The Conquering Pain Act of 2001, S. 1024, and H.R. 2156, recognize that chronic pain is a chronic health problem affecting at least 50 million Americans. These legislative initiatives seek long-lasting changes in public health policy that would enable all Ameri-

cans to effectively manage medical conditions associated with chronic pain.

Mr. Chairman, we thank you for your co-sponsorship of both H.R. 149 and H.R. 2188. Both bills advanced the cause of effective pain management.

Third, OxyContin is widely recognized as a highly effective treatment for pain. Its 12-hour controlled-release mechanism affords an extended dose of pain medication, allowing patients to sleep through the night and to avoid the sharp spikes in blood levels of medicine that can cause side effects. Even the most vocal critics of opioid therapy concede the value of OxyContin in the legitimate treatment of pain. And many patients tell their doctors and Purdue that OxyContin has given them back their lives. Purdue is furnishing for the record several documents that it has received from patients and their families describing the importance of OxyContin in managing their pain, along with a paper prepared by Pinney Associates, Incorporated, that describes OxyContin's importance to public health.

My company shares this committee's commitment to fighting abuse and diversion of controlled medicines. Abuse and diversion harm patients with pain. They harm the abusers. They harm the cause of pain management. They harm our products and they harm us. Importantly, abuse and diversion threaten sound health policy, whose course should be driven by the health needs of millions of patients, and not the crimes of diverters.

Mr. Chairman, thank you for the time you have set aside today to discuss abuse and diversion of our product. My colleagues and I will be happy to answer any questions.

[The prepared statement of Michael Friedman follows:]

PREPARED STATEMENT OF MICHAEL FRIEDMAN, EXECUTIVE VICE PRESIDENT, CHIEF OPERATING OFFICER, PURDUE PHARMA L.P.

Mr. Chairman: On behalf of Purdue Pharma L.P., the distributor of OxyContin® tablets, thank you for taking the time to hold this hearing. We are more distressed than anyone that this drug, which is providing so much relief to so many people, is being abused. The availability of OxyContin® is critical for countless patients who are suffering from moderate to severe pain where a continuous around-the-clock analgesic is needed for an extended period of time. Unfortunately for those patients, concern generated by the abuse of OxyContin® has mushroomed to the point of hysteria in some locations, with the result that some patients are asking their doctors to switch them to less effective drugs, some doctors are refusing to renew patients' prescriptions for OxyContin® and some pharmacies are no longer willing to carry OxyContin® for their patients. Purdue receives alarming reports every day from such physicians and patients. This hearing is important and timely.

Today's testimony bears on a significant question of health policy: how to address the problems of abuse and diversion which accompany the sale of a controlled drug like OxyContin® without restricting its availability to meet the needs of doctors and patients for the effective management of pain? This question is neither new nor unique to OxyContin®. It has existed as long as opioid analgesics have been available. It is a critical question, and we are confident that Purdue has devoted more resources and efforts than has any pharmaceutical company in attempting to answer that question. Purdue has provided, and continues to provide, extensive assistance to the medical and law enforcement communities in preventing and policing abuse of OxyContin®.

While all of the voices in this debate are important, we must be especially careful to listen to the patients who, without drugs like OxyContin®, would be left untreated. Purdue frequently hears stories of how OxyContin® has enabled people to return to their families and to productive lives after suffering disabling pain. We urge you to hear directly from some of these patients at future hearings. They are not addicts. They are not criminals. They are people who, because of cancer, sickle

cell anemia, severe back injuries, or some other physical insult, have had their lives taken away from them by unrelenting pain.

Amidst all the publicity and controversy, a few facts stand out.

- First, the problem of chronic pain in this country is enormous and expensive. According to organizations like the American Pain Foundation, an estimated 50 million Americans suffer from chronic pain, with a cost approximating \$100 billion a year attributable to lost workdays, excessive or unnecessary hospitalizations, unnecessary surgical procedures, inappropriate medication and patient-incurred expenses from self-treatment.

- Second, chronic pain has been historically undertreated. In this past decade, for the first time, public and medical opinion has swung decisively in the other direction, based on the proven effectiveness of opioid therapy in treating pain and the startling improvement in quality of life such therapy can offer to patients.

- In 1994, the Department of Health and Human Services issued new guidelines encouraging the use of opioids in the treatment of cancer pain.

- In February of 1999, the Veterans Administration added pain as a fifth vital sign (along with pulse, temperature, respiration, and blood pressure) that should be checked regularly as major indicators of health.

“VA officials said the change in routine is designed to call physicians’ attention to what is widely considered one of the most unrecognized and untreated symptoms in American health care. In a study of 10,000 dying patients published in 1995 in the *Journal of the American Medical Association*, for instance, researchers found that almost half died in severe pain; other studies report that as many as three-quarters of advanced cancer patients are in pain.”

Washington Post, February 1, 1999

Many other healthcare professionals and organizations have adopted this practice of checking pain as a fifth vital sign.

- On October 28, 2000, Public Law 106-386 was enacted declaring the decade commencing on January 1, 2001 to be the “Decade of Pain Control and Research.” Bills currently pending in both the House and Senate (The Conquering Pain Act of 2001, S. 1024 and H.R. 2156) recognize that “chronic pain is a chronic health problem affecting at least 50,000,000 Americans,” and seek long-lasting changes that would enable all Americans to effectively manage medical conditions associated with chronic pain.

- Third, OxyContin® is widely recognized as a highly effective treatment for pain. Its twelve-hour controlled-release mechanism affords an extended dose of pain medication, allowing patients to sleep through the night and to avoid sharp spikes in blood levels of the medicine that can cause side effects. Even the most vocal critics of opioid therapy concede the value of OxyContin® in the legitimate treatment of pain. And many patients tell their doctors and Purdue that OxyContin® has given them back their lives. Purdue is furnishing for the Record several documents that it has received from patients and their families describing the importance of OxyContin® in managing their pain, along with a paper prepared by Pinney Associates, Inc. that describes OxyContin’s® importance to public health.

Purdue shares this Committee’s commitment to fighting abuse and diversion of controlled medicines. Abuse and diversion harm patients with pain. They harm the abusers. They harm the cause of pain management, and they harm Purdue and its products. Importantly, abuse and diversion threaten sound health policy, whose course should be driven by the health needs of millions of patients, not the crimes of diverters.

1. THE COMPANY: PURDUE PHARMA.

Purdue Pharma is a privately held pharmaceutical company, founded by physicians. Purdue’s headquarters are in Stamford, Connecticut. OxyContin® is manufactured at facilities in Totowa, New Jersey and Wilson, North Carolina.

Family ownership of Purdue and its associated companies began with the purchase of The Purdue Frederick Company in 1952. In those early days, Purdue’s main products were Betadine® antiseptics and Senokot® laxatives. Since the early 1980s, Purdue has focused its research and development efforts primarily on medications for pain management. One of the most significant advances introduced by Purdue is the use of controlled-release opioid analgesics for the treatment of moderate to severe pain. Controlled-release opioid analgesics, pain medicines which last for 12 hours or more, enable patients to sleep through the night and reduce the cycles of dosing which provide better control of pain than drugs that require dosing every 4 to 6 hours. Purdue introduced MS-Contin® tablets, a controlled-release form of morphine, in 1984, and a controlled-release oxycodone product, OxyContin® tablets, in January 1996.

Since 1984, Purdue has worked diligently to inform doctors and other healthcare professionals about appropriate use of opioid based medicines. This has required a significant investment, as medical schools have traditionally spent little time teaching doctors how to assess and treat pain or how to use our best medicines for moderate to severe pain. For example, when Purdue started selling opioid analgesics in 1984, many doctors were not aware that morphine could be given orally as a treatment for pain. Today, administration of oral controlled-release morphine is considered standard practice for the treatment of cancer pain.

Purdue has extensively studied the use of these drugs in the treatment of moderate to severe pain associated with various non-malignant diseases. Often, this type of pain will only respond adequately to opioid analgesics. Without opioid therapy, many of these patients suffer and are disabled. Purdue's clinical research has provided valuable experience and data to guide physicians in properly using these medicines; for example, on determining the proper dose and dealing with side effects.

2. THE PRODUCT: OXYCONTIN® TABLETS.

No legal drug in the United States is more rigorously regulated than OxyContin®. It is a Schedule II drug under the federal Controlled Substances Act. OxyContin® is monitored by state and federal health officials in its production, marketing, and distribution. Both the FDA and DEA oversee OxyContin®.

The sole active ingredient in OxyContin® is oxycodone, a synthetic opioid (narcotic) first developed in 1916. Oxycodone has been sold in various forms in the United States for over 60 years. Percodan®, Percocet®, and Tylox® are examples of oxycodone products. Typically, but not always, these forms of oxycodone have been combined with a co-analgesic agent such as aspirin or acetaminophen, and they are referred to as "combination analgesic products". In large doses those non-opioid analgesics may be toxic to the liver, stomach and kidneys. Therefore, drugs containing either aspirin or acetaminophen are limited in their usefulness because a patient can only take up to a set amount per day to avoid aspirin or acetaminophen toxicity. Even if a patient needs more pain relief, the maximum dose of a combination analgesic cannot be exceeded. Purdue's contribution was to introduce oxycodone in a timed controlled-release form without any other active ingredients that could impose limits on the amount a patient could take in a day.

Because of the efficacy of this single entity, controlled-released product, doctors have found OxyContin® extremely effective in properly managed programs of pain treatment. That effectiveness—not abuse and diversion—led to the commercial success of the product.

3. PURDUE'S PROMOTION AND MARKETING OF OXYCONTIN® TABLETS.

Certain media reports have been critical of Purdue's promotion of OxyContin® tablets. The criticisms have ranged from Purdue's provision of pain management training to doctors to the individual promotion of OxyContin® by Purdue's sales representatives. These reports are unfair to Purdue and squarely at odds with the facts.

Purdue's marketing efforts for OxyContin® have been conservative by any standard. OxyContin® tablets are not promoted to consumers. The few advertisements that appear are solely in medical journals. Purdue is scrupulous in training its field sales force to promote OxyContin® *only* for its approved indications. Purdue managers monitor its field force for compliance with these policies. Sales representatives are told that in the event of a violation of our marketing policies, the offender will be subject to discipline, up to and including termination.

Purdue does not believe that aggressive marketing played any role whatsoever in the abuse and diversion of OxyContin®. The physicians who were victims of "doctor-shopping" or prescription fraud were hardly in this position because of our marketing. The physicians who have been convicted of improperly prescribing OxyContin® in exchange for cash or other inducements were hardly motivated to do so by our marketing. And robberies from patients with proper prescriptions were hardly encouraged by our marketing. To the contrary, our marketing has encouraged physicians to take actions that would reduce the abuse and diversion of OxyContin®. Purdue has asked physicians to carefully:

- Prescribe only the quantity of product that the physician deems is necessary based upon a complete history and physical examination and careful assessment of the patient's pain,
- Determine that the nature and severity of the patient's pain requires an opioid analgesic for an extended duration,

- Prescribe a quantity of medicine based upon the dosage that the patient requires, and
- Follow up carefully with each and every patient on a regular basis.

(a) *Purdue's training of its sales representatives.*

Virtually all of Purdue's field force is recruited from within the pharmaceutical industry. New sales representatives, despite their prior experience, are enrolled in a 26 week training program, which includes three weeks of class room training at the home office. Sales representatives are given extensive training in the principles of proper promotion of pharmaceutical products. They are directed to promote only those uses of our products which are approved by the FDA and to use only those promotional materials which are approved for use after rigorous medical, regulatory and legal review. During this training, representatives are told that our standard of conduct is that during every sales call they should act as if they were accompanied by an FDA inspector. Upon returning from their home office training, new representatives are closely monitored by their managers who will spend time in the field visiting doctors with them. In addition, field trainers from the local area and the home office will often ride with new representatives.

Moreover, in July, 2001, Purdue established a telephone "hot line" to receive comments from any physician who believes a Purdue sales representative has in any way promoted our products in an inappropriate manner. Purdue knows of no other pharmaceutical company that has gone to such lengths to insure that on a day-to-day basis its sales representatives comply with the high standards that are established during their training. The results have been reassuring; rather than being critical, the vast majority of calls to the hot line have complimented the professionalism of our sales representatives.

(b) *Physician Education.*

There is widespread consensus that medical practitioners, in the course of their medical education, have received limited and often inadequate training in the management of chronic pain. Physician education has always been a principal feature of Purdue's marketing and medical education efforts. As early as 1984 we saw that physicians wanted and needed more information about how to assess pain in their patients, how to determine the right dose of pain medicine, how to treat side effects, and more recently, how to deal with the risks of abuse and diversion. At the outset we realized that this task called for a highly professional and highly trained field force supported by an extensive medical education effort.

Purdue sponsors extensive training for the medical professional community. Specifically, Purdue sponsors local lectures at hospitals and other institutions as part of Purdue's lecture programs. These lectures are typically attended by 40 or 50 physicians or other healthcare professionals and deal with topics of interest to physicians such as pain assessment, dosing, abuse and diversion, managing pain caused by different diseases, and side effects. The lectures are often given by experts and opinion leaders in the field of pain treatment. They are held locally and Purdue does not pay physicians attending these meetings for their participation.

Purdue also sponsors symposia and lectures at larger medical meetings that are hosted by others. Purdue does not pay physicians attending these meetings for their participation.

Until a year ago, Purdue also sponsored programs to train experienced doctors and other healthcare professionals to serve as lecturers to instruct other health care professionals in pain management. These are the only trips for which Purdue provided expenses for the travel and accommodations of physicians. It would have been impractical to provide such training individually to participating doctors in their home cities rather than in one central location. These meetings were intensive working sessions that focused on issues of pain management, and also trained and evaluated the participants in effective speaking and communication skills.

4. WHAT IS THE NATURE OF THE PROBLEM?

OxyContin® is an opioid analgesic used to treat pain. Each tablet of OxyContin® delivers to the patient over a period of twelve hours, a controlled-release of oxycodone. Like morphine, OxyContin® is a Schedule II drug with recognized abuse potential. From inception, the package insert and all promotional material for OxyContin® has cautioned:

"TABLETS ARE TO BE SWALLOWED WHOLE, AND ARE NOT TO BE BROKEN, CHEWED OR CRUSHED. TAKING BROKEN, CHEWED OR CRUSHED OxyContin TABLETS COULD LEAD TO THE RAPID RELEASE AND ABSORPTION OF A POTENTIALLY TOXIC DOSE OF OXYCODONE."

Since early in the year 2000 there have been a number of reports of OxyContin® tablets being diverted and abused by drug abusers. The patterns of abuse involve crushing the tablets to obtain immediately the full dose of oxycodone and then ingesting, snorting or injecting the drug. In a number of cases, there have been overdoses and deaths. Virtually all of these reports involve people who are abusing the medication, not patients with legitimate medical needs under the treatment of a healthcare professional. Further, the vast majority of those deaths involve the use of multiple medications—not oxycodone alone.

5. WHAT IS THE SOURCE OF DIVERTED OXYCONTIN®?

According to law enforcement experts, OxyContin® and other legitimate prescription drugs find their way into illicit channels by means of prescription fraud, “doctor shopping” or other methods of receiving inappropriate prescriptions from a doctor, theft, diversion from Mexico, and Internet pharmacies. You have seen stories in your local newspapers describing some of these practices.

Unfortunately, Purdue recently had an incident that we are aggressively addressing. Purdue manufactures OxyContin tablets in two locations. These factories operate under FDA guidelines for Good Manufacturing Practices and are routinely inspected by the Food and Drug Administration and the Drug Enforcement Administration. Despite a 17 year history of manufacturing controlled substances without an incident of theft, last month Purdue discovered that two company employees had stolen OxyContin® tablets from the production line at its Totowa, New Jersey plant. Company officials immediately notified local police and the DEA and terminated the employment of these individuals, who were taken into custody by the police. Purdue as well as the local police, DEA, and FDA are conducting further investigations and Purdue is committed to full cooperation with these law enforcement agencies. All internal security procedures are being analyzed, and any weaknesses will be addressed. At this point in the investigations, we feel it would be inappropriate to comment further.

6. HOW WIDESPREAD IS THE PROBLEM?

Both Purdue and law enforcement are trying to understand the extent of this problem. Initially, the abuse of OxyContin® tablets was concentrated in a few parts of a few states, generally along the spine of Appalachia, where abuse of other prescription drugs has long been a problem due to many factors, including poverty and lack of opportunity. In those areas the problem of the abuse of OxyContin® is serious. The geographic scope is now broader. Regrettably, widespread media attention may have contributed to this wider geographic scope by calling to the attention of potential abusers in all parts of the country that OxyContin® is a desirable drug of abuse, along with providing detailed instructions on how to obtain the drug and how to abuse it.

Nevertheless, it remains difficult to obtain hard evidence on the extent of OxyContin® abuse. For example, media accounts regularly attribute large numbers of overdose deaths to OxyContin®, even though the only toxicological evidence is that the decedent has *oxycodone* in his/her blood. OxyContin® is but one of many available products that contain oxycodone. Indeed, OxyContin® tablets accounted for only 25% of the prescriptions written for oxycodone products in this country in the year 2000. Some toxicological screens of these decedents also detect the presence of acetaminophen or aspirin, a signal that some other form of oxycodone may have been ingested. In the vast majority of these so called “OxyContin deaths”, toxicological screens reflect ingestion of a “cocktail” of legal and illegal drugs, and frequently alcohol as well, in the blood of the decedent. In these cases, death is usually attributed to the abuse of multiple drugs.

While even one death associated with the abuse of OxyContin® is tragic, based on our preliminary analysis of the data, it appears that the media has significantly misrepresented the problem. This is most clearly shown by referring to the numbers of deaths the press has attributed to the abuse of OxyContin® Tablets. A few representative examples follow:

- The press indicated that Blair County, Pennsylvania was an area of high OxyContin® abuse and that a large number of people had died as a result. However, the County Coroner reported to us that there were 58 deaths in the county from January 1996 through December of 2000 and that none of them were attributed to oxycodone alone. Of the 58 deaths, 50 involved multiple drugs. Oxycodone (although not necessarily OxyContin®) was one of the drugs found in only seven cases, and was not listed as the cause of death in any case.
- The press has reported and repeated over two hundred times that in Kentucky, OxyContin® caused the deaths of 59 people. Our contacts with the State Med-

ical Examiner and local coroners establish that a number of deaths resulted from combinations of illegal and legal drugs, which occasionally included oxycodone, the active ingredient in OxyContin®. Thus far, these local authorities have not asserted that a single death was attributable to the abuse of OxyContin® alone.

—The press reported 35 deaths from OxyContin® use in Maine. Similar information from the Office of the Chief Medical Examiner showed that there were two cases where abuse of OxyContin® was the sole cause of death, one of these a suicide.

These statistics are provided not to minimize the tragedy of even a single loss of life, but as examples of how the media coverage has made it difficult to obtain an understanding of what is actually occurring. We are gathering the facts as noted from local medical examiners and coroners. In addition, according to the most recently available annual data published by the US Government's Drug Abuse Warning Network (DAWN), oxycodone in all forms, including OxyContin®, was mentioned in fewer than 1% of all prescription drug-related Emergency Room visits in which abuse was suspected. This compares with 8.7% for marijuana, 1.7% for hydrocodone (another opioid analgesic), and 3% for acetaminophen.

7. COULD PURDUE HAVE FORESEEN THE PROBLEM?

In some 17 years of marketing MS-Contin® Tablets, a controlled-release form of morphine—a powerful opioid analgesic related to oxycodone—Purdue was aware of no unusual experience of abuse or diversion. Purdue had no reason to expect otherwise with OxyContin®. As late as January of 2000, US Attorneys Jay McCloskey of Maine and Joe Famularo of Kentucky were advised by the DEA that abuse of OxyContin® did not appear to be a national problem. It was early in April of 2000 that Purdue was first alerted to reports of abuse and diversion of OxyContin® by accounts in Maine newspapers claiming that OxyContin® was the subject of recreational use in Maine. Purdue immediately implemented a response team that included some of the Company's top executives and scientists, including those who are here today. That team has committed Purdue to an unprecedented program to combat abuse and diversion.

8. WHAT IS PURDUE DOING ABOUT THIS SITUATION?

A long term solution to the problem of prescription drug abuse includes the development of medicines that are inherently resistant to such abuse. Purdue actually has been working to develop such opioid medicines since 1996, but had originally targeted oral abuse, not injection. In 1997, Purdue met with representatives of the DEA, NIDA, and FDA to discuss this subject and seek information and advice. At that meeting, Purdue presented a plan to develop a medicine containing hydrocodone and an agent to prevent abuse by injection. Purdue was told, however, that the principal method of abuse of hydrocodone was by mouth, and not injection. As a result of this advice, Purdue launched an effort to develop medicines that would be resistant to oral abuse. This was and is a formidable undertaking as there was no existing proven technology to achieve this goal. As a result of this effort, Purdue developed several technologies that should enable us to achieve the goal of having an opioid medicine that is resistant to abuse by the oral route as well as by injection. This was recently announced in the press.

The majority of law enforcement officials who have commented have lauded Purdue's initiatives described below. The Attorney General of Virginia said that as soon as Purdue learned of the problem, "it jumped in with both feet" to solve it. The Attorney General of Maryland praised Purdue's efforts and proposals and expressed concern that adverse publicity might make it more difficult for patients in need to obtain the product. Several United States Attorneys have complimented Purdue for its cooperation and have requested that Purdue bring its anti-abuse and diversion programs to their region. In several cases the United States Attorney or his assistant has actually appeared on such programs.

Purdue's efforts to solve the problem have included the following:

- Purdue approached and worked with FDA on labeling changes to emphasize the abuse potential of OxyContin®. Those changes were effected on July 18, 2001. FDA has called for other drug companies to follow Purdue's lead in making such changes.
- To reduce the incidence of diversion caused by physician prescribing errors or "scams", Purdue has supported continuing medical education programs of the highest quality in the areas of abuse and diversion. These are non-promotional programs which teach doctors how to avoid being "scammed" by abusers, how

- to properly assess and treat patients with real pain and how to prevent diversion.
- To encourage physicians and pharmacists to take measures to prevent abuse and diversion, Purdue has communicated extensively on this subject with healthcare professionals. Abuse and diversion brochures, developed in cooperation with law enforcement authorities, have been distributed to over 500,000 doctors and pharmacists. These brochures have been praised by law enforcement and welcomed by healthcare providers.
 - To encourage physicians to properly assess pain and monitor the use of these drugs in patients with pain, and avoid inappropriate prescribing or being misled by diverters, Purdue has distributed “opioid documentation kits” for years.
 - To reduce the fraud that is generated by diverters altering or copying prescriptions, in 16 states, Purdue has provided at no cost to physicians, prescription pads utilizing special technologies that make such alteration and copying extremely difficult. 4667 physicians had ordered these pads as of August 17, 2001.
 - To stop diversion that results from doctor shopping, Purdue has supported the implementation of Prescription Monitoring programs and federal government incentives to states to encourage them to implement such programs to a federal standard that insures accurate gathering of data, together with limited access to the databases only by authorized law enforcement officials and health care professional. We understand that these programs, which would provide physicians and pharmacists with a resource they could utilize to check up on questionable patients, have been highly useful to physicians and law enforcement authorities in those states where they have been implemented to a high standard.
 - Purdue has taken strong measures to prevent diversion of its product from Mexico. We believe that these steps are unprecedented in the pharmaceutical industry. Purdue has stopped shipping the 40 mg strength to Mexico and changed the markings on the 20 mg and 10 mg tablets sold in Mexico, so that law enforcement will be in a position to identify tablets that are brought in from Mexico. In addition, Purdue has made arrangements so that OxyContin® sold in Mexico will have limited distribution only through pharmacies that handle the most restricted category of opioid analgesics available in Mexico.
 - To better our understanding of the problem, and to participate in solutions, some of the most senior executives from Purdue have traveled to states where abuse and diversion have been reported to hold briefing meetings with law enforcement officials, including U.S. Attorneys and Attorneys General. We have also met with the DEA, FDA and NIDA.
 - Due to a paucity of reliable data on the nature and extent of the problem of prescription drug abuse, Purdue has been working with government and independently to develop hard data. Purdue has assembled a team of experts to guide us in the development of a system that will enable us to monitor abuse and diversion and allow constructive intervention, when possible.
 - As discussed above, Purdue is spending tens of millions of dollars to research and develop new forms of strong pain relievers which would be resistant to abuse while at the same time provide safe and effective pain relief to legitimate patients. We are working with the FDA to accelerate the availability of these drugs.

9. IS RESTRICTING THE USE OF OXYCONTIN® THE SOLUTION?

Some have suggested that restricting availability of OxyContin® will help alleviate the problem. We are convinced this is not so. Those intimately involved with the problem agree. Local law enforcement officers have told us that in most of the reported cases of overdose and death, OxyContin® was neither the first nor the sole drug abused. Knowledgeable law enforcement officers have said that if OxyContin® were not available, those abusing and diverting drugs would not stop their practices, but would simply transfer to other legal and illegal drugs. We are advised by law enforcement that in at least one area where effective measures have reduced the availability of OxyContin®, abusers and diverters have in fact returned to their prior drugs of abuse. The only real impact of restricting the availability of OxyContin® tablets would be to make it more difficult for the patients who benefit from this drug to obtain it.

10. WHAT IS THE SOLUTION?

Solving the problem of drug abuse requires the cooperation of many elements in our community: law enforcement, the schools, religious institutions, parents and family, the courts, the medical community, the press, federal and state legislators,

government agencies, social services providers, and the pharmaceutical industry. Purdue is trying to help through our specific programs and our cooperation with the other elements in the community. Prescription Monitoring Programs can reduce doctor shopping and diversion from medical practices. Tamper resistant prescriptions can reduce copying or alteration. Education of responsible doctors can arm them with the tools they need to stop diversion from their practices. A better information system can allow us to know where abuse and diversion is cropping up and allow medical education and law enforcement to act earlier to “nip these problems in the bud.” Development of abuse resistant products can reduce the incidence of abuse. What is needed is cooperation and common purpose. This is a long-standing societal problem that requires a reasoned solution.

11. CONCLUSION.

The management of chronic pain is a critical priority of healthcare in this country. Chronic pain affects as many as 50 million Americans and costs the country \$100 billion annually. OxyContin® has proven itself an effective weapon in the fight against pain, returning many patients to their families, to their work, and to their ability to enjoy life. That advance should not be stunted or reversed because of the illegal activities of those who divert and abuse the drug. The answer to these problems is increased education, information and enforcement, not restrictions that will deny patients effective treatment of their pain.

Mr. GREENWOOD. Thank you very much for your testimony. We will now hear from Dr. Michael—I have been saying Levy and Levy. Which is it?

Mr. LEVY. Levy.

Mr. GREENWOOD. Levy. Dr. Michael Levy, Vice Chairman of Medical Oncology, Director of Supportive Oncology, and Director of the Pain Management Center at the Fox Chase Cancer Center. Mr. Levy, the floor is yours.

TESTIMONY OF MICHAEL H. LEVY

Mr. LEVY. Thank you. Thank you, Chairman Greenwood, and, Mr. Bass, for inviting me to speak at this hearing. I also am the Director of the Pain Management Center at Fox Chase Cancer Center, which is just about 15 minutes from here. And I think, given the content of our discussions, I would also note that I am the father of an 18-year-old daughter and a 21-year-old son, and have sensitivities to all of the issues.

We see over 500 new patients in pain at our pain center each year, and at least a third of them have pain that is not, in fact, due to their cancer. So we see both chronic noncancer and cancer pain in patients with a history of cancer.

I have spent the last 20 years of my career as an advocate, both individually and in national organizations, to improve pain management, pain assessment, organizations, such as the American Society of Clinical Oncology, the American Medical Association, the American Pain Society, and the American Academy of Hospice and Palliative Medicine, of which I was President in 1999.

We are in the midst of two epidemics, the epidemic of unrelieved chronic pain, and the epidemic of OxyContin abuse. I speak today on behalf of the patients with chronic pain and the health care providers that care for them. The cure for the current OxyContin abuse epidemic must not increase the suffering of legitimate patients with chronic pain.

OxyContin is one of the best painkillers that we have had available to us in the last decade. Ready access to it is essential to our ability to provide safe and effective comfort and function to thousands of patients throughout the country.

To summarize the more scientific content I had in my written testimony, the cornerstone of the management of moderate to severe chronic pain is pharmacologic management. And we do that by an individual-tailored program of analgesic, and what we call coanalgesic medications, to get the best comfort and function for each patient. Optimal medical management requires us to select the best analgesic, the right dose, the right route of administration, the right schedule at the right interval. We are looking as a goal of dealing with persistent pain, of pain prevention, with then having breakthrough medications available for episodic or intermittent pain.

Effective pain relief requires aggressive adjustment of the dose of the analgesic, prevention, and anticipation and management of side effects, the utilization of specific coanalgesic drugs based on the source of pain, and consideration of sequential trials of opioid analgesics. Much like hypertension medicines, arthritis medicines, each patient has a different reaction to each analgesic, and having a variety of them to find what is the best one to give comfort and function, has become an increasingly important tool for us.

We have heard about the use of the Schedule II medications, which are on the World Health Organization's Ladder 3. They are the main medicines that we need to use in our patients who have moderate to severe pain. These medicines include Oxycodone, Morphine, Hydromorphone, and Fentanyl. The non-opioid analgesics, like Tylenol or Motrin, or the combination of Tylenol or Motrin with Codeine or Hydrocodone, have some role in acute episodic pain, but have either dose-limiting side effects or their own organ damage from the Tylenol and the Motrin that is not found in the single entity Schedule II drugs.

Morphine has been the most common Schedule II, Step 3 opioid that we have used in this country, and the standard for pain prevention was set with MS-Contin, the controlled-release form of Morphine, unlike OxyContin, being the controlled-release form of Oxycodone. MS-Contin became into our hands over 17 years ago and it has been the standard for providing good pain prevention with twice-a-day, 12-hour dosing.

We started using Oxycodone in combination products, as you have heard other testimonies, Percocet, Percodan, and Tylox. These agents were limited in two ways for our severe pain patients. We couldn't give more than three Percocet without risking a person to have liver or kidney damage with too much Tylenol or Acetaminophen or too much aspirin and, with Hydrocodone then, too much Ibuprofen.

Single-entity Oxycodone became available approximately 10 years ago. And we quickly found in our clinic, and the literature supported, that there were many patients who had less side effects, better comfort and function with Oxycodone. But until 5 years ago, we were limited to having patients have to take their medicines then every 4 hours.

We also found, when we were using short-acting Oxycodone, that there was less social stigma to Oxycodone. The patients who had been taking their Percocet or their Tylox or their Percodan after their injury, their car accident, their fracture, weren't as afraid of it as they were of anything that would contain Morphine. We then

were able to extend the use of short-acting Oxycodone with the long-acting OxyContin and found that it was effective on a twice-a-day dose. Studies showed that it was effective for the control of pain caused by cancer, osteoarthritis, post-herpetic neuralgia, major surgery, and even degenerative spine disease. Studies showed that it was comparable and preferable to short-acting Morphine and to short-acting Oxycodone.

In combined studies, OxyContin, on a milligram-per-milligram basis, is approximately two times as potent as MS-Contin. I could find no data in my review of the literature, or our clinical experience, that there was anything to say that Oxycodone had any greater risk for addiction than Morphine, Hydromorphone, or Fentanyl.

OxyContin has been crucial for the relief of chronic pain because it has what we feel the characteristics of an ideal opioid. It has a short half life, so it doesn't accumulate like Methadone can. It has a long duration. We can give it twice a day and get better quality of life. It has very predictable pharmacology. That its dose relationship, its prediction, the variation from one patient to another, is much less than most of the other medications. It also does not have clinically active breakdown products, which has been reported in the last decade as being a problem with many patients who are taking high doses of Morphine.

Its formulation also allows it to work even quicker than MS Contin when taken appropriately, so it makes it easy to get someone comfortable quickly. There is no ceiling, as there is—as there was with Codeine. Studies have shown there is less side effects, particularly hallucinations, dizziness, and itching, and, up until now, there was minimal associated stigma. It was much easier for us to say you have been on Percocet. We can get you better pain relief with less danger to your liver by using OxyContin, which is the long-acting form of the medicine in Percocet than it would be, we need to use MS-Contin because the public had this fear of Morphine.

The stigma has been a real issue. I think one of the reasons that I see for the rapid rise in the appropriate use of OxyContin is that patients and physicians have been comfortable and know how to safely and effectively use Percocet and Tylox, but were afraid of Morphine. So when we got a medicine that was, okay, I know how to use Percocet. This is now the more effective better quality of life.

Not only did we have better acceptance by our patient, but we had better utilization by orthopedic surgeons, by rheumatologists, by people treating very painful diseases or procedures who traditionally would not have used Morphine, were providing good comfort and function to these other chronic pain patients with OxyContin.

As we have seen it in our very ill patients, because of its better chemistry, particularly in the patients with a very narrow window, those patients have been very—have benefited a lot in getting less side effects, particularly nausea or sedation.

The rapid escalating abuse of OxyContin is a double tragedy. And we have heard from the first panel that there are things that we don't want to happen in our society. But we also have things that we don't want to happen in our patients after we spent the

last 20 years trying to teach them how to report their pain, advocate for appropriate pain relief.

This first tragedy is that the disease of addiction has found a new substance to abuse that, as has been mentioned, has a legal, pharmacy-based, distribution system created for the needs of appropriate chronic pain patients and the research and patient advocacy efforts of a legitimate, FDA-approved pharmaceutical corporation. This abuse violates the specific instructions of the FDA-approved OxyContin package label that states that it should only be taken orally and used for moderate to severe pain and should not be chewed or crushed.

OxyContin abuse has increased the street value, as we have heard, and led to violent crimes from abuse pushers—abusers, pushers, and prescription diversion, by deviant physicians and pharmacists. The popularity of OxyContin abuse by addicts has also resulted in the inadvertent deaths of inexperienced drug abusers who were not tolerant to other opioids and were not aware of the relative potency of the different formulations of OxyContin.

The second tragedy of OxyContin abuse is the fact that legitimate patients are having increasing difficulties in obtaining their appropriately prescribed OxyContin. The extensive media coverage of OxyContin abuse has made our patients afraid of taking their OxyContin due to resurfacing of their concerns of addiction and tolerance that we had dealt with appropriately with our patient education and support by our nurses and pharmacists and doctors when they first received their prescription. They are afraid of becoming victims of violent crime. They are—the reduced stigma that Oxycodone possessed has basically been destroyed.

Even when patients have their concerns about OxyContin resolved by their health care providers, they are being pressured by their friends, family, and uniformed health care professionals to stop using it. My nurses and I have spent an additional 15 to 20 minutes of patient education in the last few months, counseling patients to just get them to use this excellent medication. Finally, as part of the efforts to reduce OxyContin abuse, pharmacies and prescription benefit programs are restricting sales, making it increasingly difficult for honest patients to obtain ready access to their appropriately prescribed OxyContin.

Mr. Bass, you asked about remedies. State and Federal bodies and regulatory agents much take care not to increase the suffering of chronic pain patients by reducing access to adequate supplies of legally prescribed OxyContin in their efforts to control illegal OxyContin abuse.

The medical community finds itself in a very tight spot. Heroic efforts have been spent over the last 20 years to improve pain management, to dispel the myths of opioid addiction and tolerance, yet study after study after study have documented that approximately 50 percent of patients with chronic pain are undermedicated.

Beyond the Veterans Administration process that Dr. Friedman mentioned, the Joint Commission on Accreditation of Healthcare Organizations found it necessary to develop new standards for pain control to hold health care organizations accountable for the system-wide inadequacy. The National Cancer Policy Board of the Institute of Medicine and the National Research Council recently, in their

June report to the Congress, documented the persistence of unrelieved suffering in patients with advanced cancer and made specific recommendations to break down the barriers to excellent palliative care.

The National Comprehensive Cancer Center and the American Cancer Society released in April Cancer Pain Treatment Guidelines for Patients to empower them and their families to seek out and obtain state-of-the-art cancer pain management. These efforts have increased the public expectation of effective pain management, as recently demonstrated in the California case of a physician being successfully sued for failure to relieve his patient's pain.

Just when physicians are advocating or being pressured to provide better pain management, one of our best tools is being threatened. We have made significant gains in our fight to relieve pain and suffering, especially where medical science cannot eliminate the cause of that pain. We must not let these gains in preserving human dignity be lost.

In conclusion, interventions aimed at reducing the public problem of OxyContin abuse must not interfere with the safe and effective use of OxyContin for the patient problem of unrelieved chronic pain. We must join together to halt both of these terrible epidemics, unrelieved pain and opioid abuse. The resolution of either of these tragedies must not intensify the severity of the other. We must work together to heal our society and reduce the suffering of its citizens.

I, again, thank you for this opportunity to speak and look forward to responding to your questions.

[The prepared statement of Michael H. Levy follows:]

PREPARED STATEMENT OF MICHAEL H. LEVY, VICE-CHAIR, DEPARTMENT OF MEDICAL ONCOLOGY, DIRECTOR, SUPPORTIVE ONCOLOGY PROGRAM, DIRECTOR, PAIN MANAGEMENT CENTER, FOX CHASE CANCER CENTER

PHARMACOLOGIC MANAGEMENT OF CHRONIC PAIN

There are four basic approaches to pain control: modify the source of pain, alter central perception of pain, modulate transmission of pain to the central nervous system, and block transmission of pain to the central nervous system (Jacox et al 1994, Levy 1996, Doyle et al 1997, American Pain Society 1999). Systemic pharmacologic management aimed at the first three of these approaches is the cornerstone of the treatment of most patients with moderate to severe pain (Jacox et al 1994, Levy 1996). Optimal pharmacologic management of pain requires selection of the appropriate analgesic drug, prescription of the appropriate dose, administration of the analgesic by the appropriate route, scheduling of the appropriate dosing interval, prevention of persistent pain and relief of breakthrough pain, aggressive titration of the dose of the analgesic, prevention, anticipation, and management of analgesic side effects, utilization of appropriate coanalgesic drugs, and consideration of sequential trials of opioid analgesics (Table 1.) (Levy 1996).

The World Health Organization created a Three-Step Analgesic Ladder in 1990 (World Health Organization 1990). Step 1, non-opioid analgesics such as acetaminophen and non-steroidal anti-inflammatory drugs are limited to the treatment of mild pain due to their low maximal efficacy and their potential for end-organ toxicity. Step 2 opioid drugs such as codeine, and hydrocodone, and oxycodone are limited to the control of moderate pain due to the intrinsic dose-limiting side effects of codeine, their dose-limiting, fixed combinations with non-opioid, Step 1 analgesics, and their availability only as immediate-release formulations. Relief of moderate to severe acute and chronic pain is best achieved with an opioid analgesic from Step 3 of the WHO Analgesic Ladder: morphine, oxycodone, hydromorphone, or fentanyl (Jacox et al 1994, Levy 1996, American Pain Society 1999). Morphine has been the most commonly used Step 3 opioid analgesic for past thirty years. The introduction of MS Contin (controlled-release morphine), twenty years ago, set the standard for

the control of chronic pain with just twice-a-day, analgesic dosing (Hanks 1989, Thirwell et al 1989).

OXYCONTIN: AN IDEAL OPIOID ANALGESIC

Oxycodone became extended from Step 2 to Step 3 with the availability of single-entity immediate-release oxycodone (IRO) tablets and liquids. Clinical studies and practical experience with these formulations showed that oxycodone had no apparent dose ceiling, less side effects than other opioids in individual patients, and less social stigma than morphine (Kalso and Vaino 1990, Glare and Walsh 1993, Levy 1996). OxyContin has been available in the USA for five years and has been shown to be effective in the control of pain caused by cancer (Hagen and Babul 1997, Citron et al 1998), osteoarthritis (Caldwell et al 1999, Roth et al 2000), post-herpetic neuralgia (Watson and Babul 1998), major surgery (Sunshine et al 1996), and degenerative spine disease (Hale et al 2000). OxyContin is comparable and preferable to IRO and is comparable to MS Contin for the control of cancer pain (Bruera et al 1998, Kaplan et al 1998, Mucci-LoRusso et al 1998). OxyContin is approximately twice as potent as MS Contin on a milligram per milligram basis (Bruera et al 1998, Curtis et al 1999).

OxyContin has the characteristics of an "ideal" opioid analgesic drug: short half-life, long duration of action, predictable pharmacokinetics, absence of clinically active metabolites, rapid onset of action, easy titration, no ceiling dose, minimal adverse effects, and minimal associated stigma (Table 2.). Oxycodone has a serum half-life of 3-5 hours with steady state reached in 24-36 hours (Kalso and Vaino 1990, Glare and Walsh 1993). Double-blind studies have shown that OxyContin given every 12 hours is as effective as an equivalent dose of IRO given every 6 hours (Kaplan et al 1998, Hale et al 2000). OxyContin has a biphasic absorption with a minor, initial peak at 0.6 hours and a secondary, major peak at 6.2 hours (Kaiko et al 1996b, Mandema et al 1996, Benziger et al 1997). Clinical analgesia has an onset within 1 hour and a duration of 12 hours (Mandema et al 1996, Sunshine et al 1996). The bioavailability of oxycodone is 60-87% which increases the predictability of its pharmacokinetics (Kalso and Vaino 1990, Kalso et al 1991, Reder et al 1996). Clinically, the predictable pharmacokinetics of OxyContin are demonstrated by the independence of its dissolution on pH and the high correlation of its dose with its plasma level (Kaiko et al 1996b, Benziger et al 1996, Kaiko 1997, Mucci-LoRusso et al 1998, Mandema et al 1998). OxyContin's bioavailability is increased by 15% in the elderly and approximately 50% in renal dysfunction (Kaiko et al 1996b, Kaiko 1997, Mucci-LoRusso et al 1998, Mandema et al 1998). OxyContin has less plasma variation than morphine (Colucci et al 1998) and has no clinically significant active metabolites (Kaiko et al 1996a, Heiskanen et al 1998). The time-action of oxycodone's drug effect coincides with its time-concentration. Its drug effect is not altered by inhibition of oxymorphone formation with quinidine (Kaiko et al 1996b, Heiskanen et al 1998). Because of its biphasic absorption, OxyContin has an onset of pain relief of 46 minutes, which is almost as rapid as the analgesic onset of IRO at 41 minutes (Sunshine et al 1996, Kaiko 1997). The mean time to peak pain relief for 40 mg of CRC is 1:29 hours compared to 2:20 hours for MS Contin (Sunshine et al 1996, Kaiko 1997). Combined data from several controlled studies with OxyContin and MS Contin showed that OxyContin was easily titratable and had no ceiling dose (Kaiko et al 1996b, Heiskanen and Kalso 1997, Mucci-LoRusso et al 1998, Bruera et al 1998, Curtis et al 1999). The average daily dosage of OxyContin in these studies was 120 mg with an equianalgesic ratio of morphine to oxycodone of 2:1 (Mucci-LoRusso et al 1998, Bruera et al 1998, Curtis et al 1999). Common opioid-induced adverse effects were minimal with OxyContin and diminished over time with the same tolerance observed with other opioids (Bruera et al 1998, Kaplan et al 1995). Fewer patients taking OxyContin experienced severe adverse effects and more had no adverse effects compared to patients taking MS Contin (Mucci-LoRusso et al 1998). Patients taking OxyContin experienced less hallucinations and dizziness (Mucci-LoRusso et al 1998, Reder et al 1996, Weinstein et al 1998) or scratching and itching than those taking MS Contin (Mucci-LoRusso et al 1998). This latter observation might be accounted for by the speculation that oxycodone may have less propensity to stimulate histamine liberation than morphine (Flacke et al 1987, Poyhia et al 1992). Clinical practice has shown that oxycodone has less associated stigma than morphine. Many healthcare providers and patients associate morphine, but not oxycodone, with advanced illness, impending death, and high risk of addiction (Fitzmartin and Reder 1995). In the United States, combinations of oxycodone plus acetaminophen or aspirin have been used for years as Step 2 opioids for moderate chronic pain and moderate to severe acute pain resulting in greater familiarity and comfort with prescribing and

taking oxycodone than morphine (Reder and Fitzmartin 1995, Levy 1996, Caldwell et al 1999). OxyContin's freedom from acetaminophen or aspirin facilitates upward dose titration and its 12-hour duration provides a significant patient convenience over 4-hourly immediate-release opioids. OxyContin has been shown to decrease pain and improve function in osteoarthritis (Caldwell et al 1999, Roth et al 2000), post-herpetic neuralgia (Watson and Babul 1998), major surgery (Sunshine et al 1996), and degenerative spine disease (Hale et al 2000)

In summary, OxyContin is comparable and preferable to immediate-release oxycodone for the control of chronic cancer pain. OxyContin is comparable to MS Contin for the control of chronic cancer pain and is approximately twice as potent as MS Contin on a milligram per milligram basis. MS Contin is also effective for the control of osteoarthritis pain, post-herpetic neuralgia, acute post-operative pain, and chronic low back pain. OxyContin has the attributes of an ideal opioid: short half life, long duration of action, predictable pharmacokinetics, no clinically significant active metabolites, rapid onset of action, easy titration, no ceiling dose, minimal adverse effects, and minimal associated stigma (Evans 1999). Its multiple dosing forms permit its early use and individualized titration to optimal comfort and function in most patients with moderate to severe pain. The benefit of OxyContin can be optimized by the use of immediate-release oxycodone for breakthrough pain and would be greatly facilitated by wider access to parenteral oxycodone for patients temporarily unable to use the oral route. Its potential for less adverse side effects, relative to morphine, might be even more advantageous for sicker patients with narrow therapeutic windows for opioid analgesics.

OXYCONTIN ABUSE: A DOUBLE TRAGEDY

The rapidly escalating abuse of OxyContin in the last year is a double tragedy. The first tragedy is the fact that individuals with the disease of addiction have found a new substance to abuse that has a legal, pharmacy-based, distribution system created by the needs of appropriate chronic pain patients and the research and patient advocacy efforts of a legitimate, FDA-approved pharmaceutical corporation. OxyContin abuse by these individuals has led to violent crimes by these individuals and to prescription diversion by deviant physicians and pharmacists to profit from OxyContin's increased street value. The popularity of OxyContin abuse by addicts has also resulted in the in the inadvertent deaths of first time drug abusers who were not tolerant to opioids and were not aware of the relative potency of the different formulations of OxyContin available.

The second tragedy of OxyContin abuse is the fact that legitimate pain patients are having increasing difficulty utilizing their appropriately prescribed OxyContin. The extensive media coverage of OxyContin abuse has made patients afraid of taking their OxyContin due to resurfacing of their concerns of addiction and tolerance that had been accurately addressed by their physicians and nurses when they received their first prescription. Patients are also afraid of being victims of violent crime by addicts or dealers who want their prescriptions or their OxyContin pills. The reduced stigma that oxycodone once possessed compared to morphine has decayed. Even when patients have their concerns about using OxyContin resolved by their health care providers, they are being pressured by their friends, family, and uninformed, health care professionals to stop using it. Finally, as part of their efforts to reduce OxyContin abuse, pharmacies and prescription benefit programs are restricting OxyContin sales, making it increasingly difficult for honest patients to obtain ready access to their appropriately prescribed, OxyContin.

REMEDIES FOR OXYCONTIN ABUSE MUST NOT INTERFERE WITH RELIEF OF CHRONIC PAIN

Regulatory agencies such as the FDA and DEA must take care not to increase the suffering of chronic pain patients by reducing access to adequate supplies of legally prescribed OxyContin in their efforts to control illegal OxyContin abuse. Despite heroic efforts over the past twenty years by individual and organizations to redress the balance of medicine and ensure appropriate assessment and treatment of chronic pain, surveys still show that half of the patients in this country with chronic pain are undertreated. Last year, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) found it necessary to develop new standards for pain control to address this system-wide inadequacy. The National Cancer Policy Board of the Institute of Medicine and the National Research Council recently underscored the persistence of unrelieved suffering in patients with advanced cancer and made specific recommendations to break down the barriers to excellent palliative care (Foley and Gelband, 2001). The National Comprehensive Cancer Network and the American Cancer Society have just released Cancer Pain Treatment Guidelines for Patients to empower patients and their families to seek out and obtain

state-of-the-art cancer pain management. As an example of the increasing public expectation of effective pain management, a California physician was just successfully sued for failure to relieve his patient's chronic pain. Interventions aimed at reducing the public problem of OxyContin abuse must not interfere with the safe and effective use of OxyContin for the patient problem of unrelieved chronic pain.

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Mr. GREENWOOD. Thank you, Dr. Levy, for your excellent testimony, and we appreciate that. And, finally, Nurse Terry Atwood. Thank you for being with us.

Ms. ATWOOD. Thank you.

Mr. GREENWOOD. And don't be intimidated by these microphones in your face.

Ms. ATWOOD. Sure.

TESTIMONY OF THERESA ATWOOD

Ms. ATWOOD. My name is Theresa Atwood. In the recent past, I have practiced nursing in Philadelphia, Bucks, and Delaware Counties, and I am a resident of Delaware County. I am a Registered Nurse, certified by the American Nurses' Credentialing Center in the specialty of Psychiatric and Mental Health Nursing. I hold a Master of Human Services Degree and am a member of the American Psychiatric Nurses' Association, as well as the American Counseling Association.

As a mental health/addictions professional, a family member of people who suffer from, or are in recovery from the disease of addiction, and as a person who is also in recovery from this disease, I have continuous exposure to it, in its many forms, and in its various stages of progress and outcomes. I am grateful you have granted me the honor of speaking here today.

In considering the escalation of the number of people becoming addicted to, and dying from, the misuse of OxyContin, it is important to realize that its respiratory depressant effects can be lethal with any, including the initial use, that is not monitored by a physician. The likelihood of death is increased because when used in conjunction with alcohol and other sedatives, as is the practice among many teenagers, the respiratory-depressant effects are potentiated. The rapid increase in the number of young people able to access and consequently abuse OxyContin is intensely apparent in my daily practice.

Many, if not most, of the adolescents I come in contact with are well aware of how “good” the “Oxy’s” are. When I ask my young patients if they realize that OxyContin is just as, if not more, deadly than heroin, they respond with great skepticism and apathy because they view OxyContin as a medicine, not a street drug, making it more attractive to a wider variety of teens. These young people consider OxyContin to be a cleaner, prettier, more powerful form of heroin.

Although they are vastly informed of the positive euphoric potency of OxyContin, they have little, if any, information about its often fatal respiratory depressant and other side effects, and the eventual withdrawal syndrome. This lack of knowledge and lack of concern for their own existence is evident as the freely admit to, and even brag about, supplementing OxyContin use with alcohol and other opioids, a practice that has proven to have detrimental consequences.

Upon entering treatment, often as a result of legal or familial force, adolescents are resistant to intervention or education. This opposition is not only a result of their inherent developmental ideology of independence, omnipotence, and immortality, but also because OxyContin provides the ultimate in escapism. I have watched young people walk out of treatment centers, risking imprisonment, homelessness, the loss of families, including the loss of their own small children, and even the loss of their own lives, rather than face the prospect of life without OxyContin and other drugs.

The horrible dilemma of OxyContin misuse recently hit home for me. My relative had been in a car accident, suffered spinal trauma, and was being treated with Percocet for a number of years. As his tolerance to the Percocet increased, his physician began to utilize OxyContin to manage his back pain. Once he was introduced to OxyContin, he required more and more of it. He was initially prescribed 10 milligrams, then 20, then 40, 80, and finally 160 milligrams. At the conclusion of his active use, he was taking up to four 160-milligram OxyContin, with Percocet, Soma, and Fioricet, a day, an amount which, by all accounts, could have easily been fatal.

He states that once addicted, he began chewing the OxyContin, despite the accompanying nausea and gagging. He tells me that as he would be picking up a prescription, his mind would be racing to figure out a way to get the next one. He offered many excuses to physicians, such as his son spilled the pills down the sink, or his car was robbed. He admits to loss of libido, lack of motivation, outside of obtaining the pills, and wide mood swings. He says, I didn’t

want sex. I had no feelings. All that I thought about was getting the next script.

After many months, his wife began threatening to leave him and his performance and relationships at work began to suffer. This didn't happen when I practiced. He knew he needed to stop using the medications, and he states he really wanted to, but despite all thoughts, desires, and actions to the contrary, he continued and increased his use. He tells me, as I sat there watching everything I had ever wanted, my wife and family, packing up and walking out the door, I literally couldn't even move to stop it. I was so screwed up.

Currently, my family member has 96 days cleans and he just got a promotion at work, but he adds, my wife is still gone. After long-term treatment experience, he was able to obtain recovery thus far. Maintaining his recovery is difficult and requires much outside support. He now uses a non-narcotic prescription medication to manage his back pain, which he assures me works well, however, his insurance won't pay for it. Ironically, they paid over \$100,000 for the OxyContin he took. Obviously, there is a blaring need for quality treatment for those who become addicted to this medication.

To summarize, those patients for whom it is truly indicated, OxyContin is absolutely beneficial and necessary, however, for those who recreationally use it, or become addicted, it is just as powerfully destructive. Thank you all for your time and attention, and I implore you to ask me any questions you may have.

[The prepared statement of Theresa Attwood follows:]

PREPARED STATEMENT OF THERESA ATTWOOD, REGISTERED NURSE

My name is Theresa Attwood. I am a registered nurse, certified by the American Nurses' Credentialing Center in the specialty of Psychiatric and Mental Health Nursing. I hold a Master of Human Services Degree and am a member of the American Psychiatric Nurses Association as well as the American Counseling Association. As a mental health/addictions professional, a family member of people who suffer from, or are in recovery from the disease of addiction and as a person who is also in recovery from this disease, I have continuous exposure to it in its many forms and in its various stages of progress and outcomes. I am grateful you have granted me the honor of testifying here today.

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Many, if not most, of the adolescents I come in contact with are well aware of how "good" "Oxys" are. When I ask my young patients if they realize that OxyContin is just as, *if not more*, deadly than heroin, they respond with great skepticism and apathy because they view OxyContin as a medicine—not a street drug, making it more attractive to a wider variety of teens. These young people consider OxyContin to be a cleaner, prettier, more powerful form of heroin. Although they are vastly informed of the positive euphoric potency of OxyContin, they have little, if any, information about its often fatal respiratory depressant effects and the eventual withdrawal syndrome. This lack of knowledge, and lack of concern for their own existence, is evident as they freely admit to, even brag about, supplementing OxyContin use with alcohol and other opioids—a practice that has proven to have detrimental consequences. Upon entering treatment, often as a result of legal or familial force, adolescents are resistant to intervention or education. This opposition is not only a result of their inherent developmental ideology of independence, omnip-

otence, and immortality, but also because OxyContin provides the ultimate in escapism. I have watched young people walk out of treatment centers, risking imprisonment, homelessness, the loss of families—including the loss of their own small children, *and even* the loss of their own lives, rather than face the prospect of life without OxyContin and other drugs.

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To summarize, to those patients for whom it is truly indicated, OxyContin is absolutely beneficial and necessary, however, for those who recreationally use it, or become addicted, it is just as powerfully destructive.

Thank you for your time and attention.

Mr. GREENWOOD. Thank you very much for your testimony. It never happens when you practice it. It gets real here. Thank you very much. Dr. Friedman, let me begin with you. Is it Dr. Friedman?

Mr. FRIEDMAN. It is Mr. Friedman. Thank you.

Mr. GREENWOOD. Look, we stipulate, I stipulate, yours is a good company with a long and exemplary record in, as I said, in my opening statement, relieving pain. And I believe that your product and your company has done, by orders of magnitude, more to relieve pain in this country than to cause it. There is no question about that. It is also clear that, as the last witness indicated, it has caused a lot of pain, as well.

When you have a—it seems to me that when you have a product that is this powerful, and that is what this drug is, this is a powerful drug—there are a couple of things that you want to do. You want to make sure, as hard as you can, that it gets into the hands of people who are suffering. And you try—and you do that very aggressively. It seems to me, equally as obvious, that you have to do all that you can in making an equal effort to make sure that this drug is not abused to the extent that you can. And it doesn't cause anguish, because the anguish of the families sitting here to our right will go on forever over the loss of their young son.

It is clear that your company did an extraordinary job in the first case. Marketing was aggressive, even aggressive by today's market expanse. Make sure that you research the markets. You had an aggressive sales force. You have got seminars that you put on and so forth.

The question is—and you are not on trial here. The question is, has the company done enough to prevent the misdirection—you knew going into it—you had to know going into it that this is a product that is likely to be diverted to the street, it is likely to become addictive, it is likely to be stolen, it is likely to become lethal when used not according to directions.

So I guess the questions that I have for you are, what have you done along those lines and have your efforts been—you have \$1.25 billion in sales a year, if my numbers are correct, 83 percent of your revenue as a result of your very aggressive marketing. How aggressive have you been in the other half of your responsibility, and that is, to protect the public from the negative consequences of this product? And how might we be of assistance to you with regard to this product and other products in creating tools for law enforcement, tools for the monitoring of these products, education efforts? Tell us how we can be not just accusers here, but how we can be part of the solution?

Mr. FRIEDMAN. Mr. Chairman, thank you. Purdue would like to take a lead role in helping to solve this problem. And we have worked diligently, as long as we have been marketing narcotic analgesics, to market them responsibly. When we launched MS-Contin in 1984, that product required a great deal of education, because up until that time, many physicians, including oncologists, did not see the importance of the need to control pain. When we made visits to oncologists back then, we were told, at times, our job is to cure the cancer. Pain is not the focus of our practice.

But since 1984, we have seen a see change in medical thinking. But all through that time, that see change took place as a result of a great deal of education. We knew that in order to use these products properly and responsibly, physicians would need education. They would need information and they would need tools. And we have sought, through that entire period, to provide those tools.

As we marketed MS-Contin, up to the launch of OxyContin in 1995, the end of 1995, we saw very little evidence of abuse and diversion of MS-Contin. When we launched OxyContin, we saw very little evidence of abuse and diversion until some time around 2000, which, based on the testimony I have heard from other panelists, is the time that, in general, that type of abuse and diversion was noticed.

But we are doing much more than our medical education and other programs. We have been working very hard to develop products that would be resistant to abuse and diversion, as well, which we think is an important long-term solution.

Mr. GREENWOOD. I addressed some questions to the representative of the Drug Enforcement Agency about data that is available. In informal conversations with representatives of your company, I have been led to understand that there is a private entity that creates a data base that I thought provided the data in terms of prescriptions per physician, and that your company, in fact, acquires that data on an ongoing basis and has that data. Can you summarize that for us? What does your company know about how many prescriptions each physician writes for your OxyContin?

Mr. FRIEDMAN. We do acquire data very much along the lines that you describe, Mr. Chairman. We acquire it from IMS Health. IMS Health captures this data through the computers at pharmacies. Of course, certain patient information is excluded to protect the patient's right to privacy.

Mr. GREENWOOD. Like, for instance, if Dr. Paolino here in Buckingham—Bensalem, wrote 1,200 prescriptions in the 5-month period, that is data that you would have had. Correct?

Mr. FRIEDMAN. Correct.

Mr. GREENWOOD. Okay. Now, when you have that data, I would guess that one of the things that you would do with that data is arrange it so that you can take a look at—you can rank these physicians. You have some indication as to who is writing the most, who is writing the least, and in between, and who the outliers are. Do you have—do you look at that information in that way?

Mr. FRIEDMAN. Yes. The only comment that I would add is that we get the data somewhat after the actual event of the prescription. There is a 6 to 8-week lag.

Mr. GREENWOOD. Okay. But assuming that Dr. Paolino was a great outlier, very abusive individual, who wrote this without any regard whatsoever for the medical condition of the patients, wrote these prescriptions as fast as he could purely for profit-making purposes. What does your—I would think that Dr. Paolino—I would hope that he would have stuck out like a sore thumb and that there must be other Dr. Paolinos in this country who do the same—take the same kind of approach, and that that information would be aware—that your company would be aware of that kind of information. The question then is, how do you respond to that, when you see a doctor who is not associated with Fox Chase Cancer Center, and is just a little osteopath here in Bensalem, doing this vast number? What do you do with that information?

Mr. FRIEDMAN. Well, we have learned over the years that the absolute number of prescriptions that a physician is prescribing is, in and of itself, not an indicator of the doctor doing something wrong. We don't measure or assess how well a physician practices medicine. We are not in the office with a physician and a patient observing the examination or involved in that process. We know, for example—

Mr. GREENWOOD. Well, why do you want that information then?

Mr. FRIEDMAN. Well, we use that information to understand what is happening in terms of the development of use of our product in any area.

Mr. GREENWOOD. And so the use of it—and I assume that part of it—a large part of it you want is to see how successful your marketing techniques are so that you can expend money in a particular region or among a particular group of physicians—you look to see if your marketing practices are increased in sales. And, if not, you go back to the drawing board with your marketers and say, how come we spent "X" number of dollars, according to these physicians, and sales haven't responded. You do that kind of thing. Right?

Mr. FRIEDMAN. Sure.

Mr. GREENWOOD. Okay. So it would seem to me that you would also have a responsibility—see, this is what I am getting out of my first question. You took all that data and you looked at it for the

first part, to see how you were doing in the first part of your responsibility—get the product out, increase sales, increase revenues. Okay. Did you look at the data with a—in response to your last question, you said we don't look to see how physicians are practicing medicine. Well, that is the other side of your responsibility. Why wouldn't you have been using this data to make sure that the Dr. Paolinos of the world weren't wrecking the reputation of your product?

Mr. FRIEDMAN. I think Mr. Udell might be able to respond to that more further.

Mr. UDELL. One of the—

Mr. GREENWOOD. Well, perhaps he can pull up a chair and speak into the microphone, Mr. UDELL. Maybe I can stand here. There isn't a chair. Mr. Chairman, one of the things—

Mr. GREENWOOD. Well, you need to talk into this microphone here.

Mr. UDELL. Thank you, Mr. Chairman. One of the things that we learned when we visited with law enforcement around the country when this problem first arose, was what Mr. Friedman said, that drug enforcement people tell us that you can't look at prescriptions alone. You have to look at what the doctor is actually doing in the office. And apparently that happened here. But that is not something—

Mr. GREENWOOD. Well, you didn't do it.

Mr. UDELL. That happened here in terms of law enforcement.

Mr. GREENWOOD. Well, and local pharmacists saw—

Mr. UDELL. Correct.

Mr. GREENWOOD. He had rough data—

Mr. UDELL. Right.

Mr. GREENWOOD. [continuing] that you had. And he saw, from his perspective—he looked at this data and he said, Holy God, there is some guy in Bensalem—

Mr. UDELL. That is right.

Mr. GREENWOOD. [continuing] called Paolino and he is writing prescriptions out the wazoo.

Mr. UDELL. Yes.

Mr. GREENWOOD. Now, he had that data and he blew the whistle.

Mr. UDELL. Correct.

Mr. GREENWOOD. And you had that data. What did you do?

Mr. UDELL. Well, we didn't have the data that he had. We didn't know that you had a physician a distance away writing prescriptions that were filled in a particular pharmacy. I think that that is what alerted that pharmacy, at least as I understand the reports in the paper.

What I am trying to say is that our sales representatives have a couple of minutes with a doctor. They talk to the doctor about the product and they leave. Law enforcement tells us that high numbers, high numbers of prescriptions, may or may not be a signal. They may not be, even if he is not at Fox Chase, even if he is a rural physician. It is not necessarily a signal. What they have to do is, they have to get in there and try to find out. It is a very difficult task. They have explained to me again and again, that trained investigators—and you heard from Mr. Demarest earlier,

and he is one of those kinds of investigators—trained investigators can go in there and try to assess these things.

Mr. GREENWOOD. Let me interrupt you.

Mr. UDELL. Our people just don't have the—

Mr. GREENWOOD. Let me interrupt you for a second. And I don't want to be too harsh here. But, look, the law enforcement people have a million things to do.

Mr. UDELL. Yes.

Mr. GREENWOOD. And they are not getting \$1.25 billion a year to do it. They are all stretched, in terms of time, manpower, and budget. Okay.

Mr. UDELL. Yes.

Mr. GREENWOOD. It seems to me that your company has a responsibility to be looking at this data and not relying on what law enforcement tells you, but saying what does Purdue Pharma have as a responsibility to do with the data that we have that tells how many doctors are selling—which doctors are writing how many prescriptions—

Mr. UDELL. Yes.

Mr. GREENWOOD. [continuing] and how do we make sure that those are all good prescriptions, and weed out the bad actors? It is in your interest to do that.

Mr. UDELL. Yes.

Mr. GREENWOOD. And I don't understand why that hasn't been something that you have been aggressively doing.

Mr. UDELL. It is absolutely in our interest to do so. And I think that we have all learned a lot from the case of Dr. Paolino. If we are to—the story, the picture that is painted in the newspaper is of a horrible, bad actor, someone who has preyed on this community, who has caused untold suffering. And he fooled us all. He fooled law enforcement. He fooled the DEA. He fooled local law enforcement. He fooled us. None of us, until a certain point in time, had an understanding that something wrong was going on there. And I think that we all have to learn from that. I think you are absolutely correct. We have to learn from this experience and we have to examine ourselves, is there more that we can do? Is there more that DEA can do? Is there more that local law enforcement can do? Is there more that we can do?

Now, we are examining that. We have spoken to the sales representative who called on this doctor. And there came a point in time when she was alerted—she was alerted by a—

Mr. GREENWOOD. But if I can interrupt you, we have had this conversation before. And it seems to me part of the problem is that your sales force gets paid on a commission basis, and the more they sell, the better they do.

Mr. UDELL. Yes.

Mr. GREENWOOD. So it is awfully hard to imagine that they would be the people in your organization who would go out and tell the doctors you are making me too much money. You are writing—

Mr. UDELL. We would—

Mr. GREENWOOD. You are writing too many prescriptions.

Mr. UDELL. Mr. Chairman, I don't know how clearly I can put this. Our sales force understands that the survival of the company,

the product, and their livelihood, depends on them doing the right thing and making sure that the doctors who write these prescriptions write them properly. They understand that that is job No. 1.

In areas where we have seen abuse and diversion, and as I spoke with staff and discussed with staff earlier, in areas where we anticipated that there might be abuse and diversion, we have tried to get out in front of the problem. And Mr. Friedman has talked to his sales people and he has said to them, your job is not to sell OxyContin. Your job is to go in there and try to be a part of the solution and to say to these doctors, you must write these prescriptions correctly. You must keep appropriate records. You must comply with State Medical Board regulations and DEA regulations. We have tools. We have devices. We have techniques to help you do so. And if you are not prepared to do so, do not write our product. Please, do not write our product.

So while it is correct that there is a—there may be an incentive to extol the virtues of the product, there is clearly a greater incentive to make sure that the product is not written inappropriately. Dr. Paolino has done more to harm the company and the product than perhaps anyone in the country. There is no reason why we would want to do anything to support those kinds of activities or encourage them or countenance them, if we are capable of stopping it.

Mr. GREENWOOD. I am going to yield now—if there is another Dr. Paolino in the country or 10 of them, there is—my guess is that there are—some of them are going to emerge, and I hope that you would take the step to prevent that. The Chair yields to the gentleman from New Hampshire to inquire.

Mr. BASS. Thank you very much, Mr. Chairman. Sir, I think you might as well remain up there. What is your name again? I am sorry.

Mr. UDELL. Howard Udell.

Mr. BASS. Mr.—Attorney Udell, what exactly are you doing today, tomorrow, or next week, to prevent incidents like the one just discussed—

Mr. UDELL. Yes.

Mr. BASS. [continuing] from ever happening again?

Mr. UDELL. Yes. Well, perhaps Michael—perhaps, you would want to talk about the program.

Mr. BASS. Without—but, be specific, please.

Mr. UDELL. Yes. Sure.

Mr. BASS. You have the data. You know that 1,200 prescriptions in 5 months is not the norm. Perhaps, you may not have noticed it because you weren't expecting it. What are you doing now to assure that your product is not abused in any—in this manner ever again?

Mr. FRIEDMAN. Well, if I could comment briefly? When this problem first cropped up, it was a surprise to many. And when we heard about the problem, we first had to go learn more about it. And personally, I have traveled to visit the Attorneys General in 10 States where the problem seemed to be most prevalent. I have met with—when the problem was first identified with U.S. Attorney McCloskey in Maine and U.S. Attorney Crouch in Virginia, at those meetings, they helped us to understand the problem and

helped us define things we could do that were beyond the things we were doing at that time.

We also learned the nature of the problem. Because the first question that I asked was, where is this coming from? What is the source of this diverted drug? And what we were told, at the time, and what seems to be the prevalent thinking today, is that the first source is some kind of prescription fraud, copied prescriptions, altered prescriptions, stolen prescriptions. A second type of problem is some kind of fraudulent prescribing or error in prescribing. And we tried to set up programs working with law enforcement that would address those specific things. So, for example, we developed a program and a campaign to provide physicians with tamper-resistant prescriptions.

But one of the other things we recognized that we needed, and others needed, was information. In order to identify a Dr. Paolino, or some other person abusing—you know, writing drugs that was creating a pattern of abuse, we needed a system for figuring that out. We didn't know how to identify abuse.

And so what we did was, we, first of all, looked at the available data sources. But since that time, what we have done is we have convened a panel of experts to help us design a data-gathering system, an information system, and a warning network for ourselves. Because absent such a system existing, we need some way of reaching out and understanding where is abuse going on. Because we have learned that the number of prescriptions is not indicative, in and of itself, of abuse. We need to know more. And these experts are helping us develop such a system so that we can identify the places where abuse and diversion is going on and design some kinds of interventions.

Mr. BASS. Okay. Tell me, Mr. Friedman, that you consider this issue to be a crisis for your company. You have got \$1.27 billion apparently in revenues. You have the resources to be very aggressive, and you have the interest to do it, as well. And understanding the nature of the problem, developing information, and establishing a panel to study it, and to try to understand it. The mysteries of it are certainly commendable. But those things ought to be done in a matter of weeks, not months or years. You ought to have—and it is none of my business—but you ought to have an office within your organization that is responsible for internal investigations and develop relationships with law enforcement community, because it isn't in your best interest to have these people writing all these prescriptions like this.

And, frankly, I am not impressed with panels and study problems, and calling people on the telephone to try to figure it out. You have access to the data already. Now, I mean, that seems to be obvious to me. But there are other things that you could do. And I wanted to know if I could ask—first of all, I would love it if you would tell me that you are going to be more aggressive in establishing panels and trying to understand the issue better—that you are really going to do something to solve it, that is substantive, quick, and effective.

Second, let me ask you, are there other things that the company might consider doing, for example, restricting the distribution of

this drug to certain physicians and certain pharmacies that are really qualified to dispense this prescription?

Third, adding substances to the drug that would make it impossible or reduce its toxicity if it were crushed or taken in other—in an adverse manner?

Mr. FRIEDMAN. Well, first of all, I would like to say that I can tell you that we will be more aggressive and we will do as much as we can to solve the problem.

Mr. BASS. Can you keep the subcommittee informed as to that progress?

Mr. FRIEDMAN. Yes, sir.

Mr. BASS. Thank you.

Mr. FRIEDMAN. And insofar as the question of what we can do about a new—adding substances or making abuse-resistant formulations, I might ask Dr. Goldenheim to provide some comments.

Mr. BASS. Before he does, can you address the third issue, which is the restriction of sales to people who are really outside a general practice or to any—that issue?

Mr. FRIEDMAN. Yes.

Mr. BASS. I can't think of any other ways to deal with the issue.

Mr. UDELL. Restricting sales has been described to us in two ways. One is restricting the types of doctors who would use these drugs, and the second is restricting certain—distribution to certain pharmacies. I think, Mr. Bass, you alluded to both of those.

Mr. BASS. Yes.

Mr. UDELL. With respect to the first, it is a terribly difficult problem. We understand that there are about 4,000 pain specialists in the United States. There are vast numbers of patients who need drugs, such as OxyContin, who don't have access to those doctors. Now, what happens, even in the case of cancer patients, who are at the prestigious institutions, cancer centers, when they go back home into the community, their pain is managed by their family physician. So it is very difficult to say you are going to restrict access only to specialists, because to do so would be to deprive the vast majority of people who need it, of these drugs.

On the other hand, DEA has said, and we totally agree with DEA on this, is that physicians should not use drugs like this unless they know how to use them. Whether they are pain specialists, or whether they are family physicians, they should know how to use them. And the other is a role for us, and it is a role that we undertake willingly and happily, and that is, to try to help these doctors understand how to use these drugs.

And the programs that Mr. Greenwood spoke about, programs that we have put on, to teach doctors how to use these drugs responsibly and appropriately, have been invaluable. And they have been directly applicable to solving the problem.

For example, in the State of Kentucky, when the United States Attorney, Mr. Famularo—I saw him on television and he had made an arrest of 200-plus people involved in drug trade—prescription drug trade. I called him in the morning, the very next morning, and I said to him, we distribute OxyContin. OxyContin played a major role in the large drug bust that I read about yesterday. We want to help be a part of the problem. How can we help you? And we start—we embarked on a conversation of what we can do to

help that problem in Kentucky. And what was very important to him is this very subject—education. He said we have a lot of doctors who don't understand how to use these drugs. They need education. Can you help us with that? And we did.

We established a group, together with the United States Attorney's Office. He designated an Assistant United States Attorney to work with us, and together, we put on programs in the community where there was the greatest abuse, to try to deal with the problem. And Mr. Famularo, himself, attended those programs.

Even earlier, when we first heard of this problem, the very earliest time—it was very interesting that Mr. Woodworth said that he knew about it earlier than this and he assumed that we did. And that was a surprise to me because Mr. McCloskey, who was the United States Attorney in Maine at the time, told me that when he started to see that problem, at the very earliest, at the beginning of 2000, he reached out to the DEA for information and the DEA people with whom he spoke said, they don't know of an OxyContin problem. They are unaware of an OxyContin problem.

And that brings us right to the point that was made by the District Attorney of Bucks County. I think that she made a wonderful point. Cooperation and sharing of information is essential. And if some element in the DEA knew there was a problem, Mr. McCloskey should have known about it. He is the United States Attorney. He should have gotten an affirmative response. We should have known about it. And we didn't know about it. And we didn't know about it. We knew about it after it pulsed up in Maine and the press reported it. And, again, the first thing we did was we said, we want to go up and see you. We want to meet with you, and we did. And we met with Mr. McCloskey.

And, again, Mr. Bass, in answer to your specific question, we acted very quickly. At that meeting, we said to Mr. McCloskey, we want to work together with you to solve the problem in Washington County, Maine. How can we do it? And what we—and what came out of that meeting was, we said to him, we call on all the doctors in this community, the doctors who write these prescriptions. We can deliver a message to these doctors. And, frankly, the message that we want to deliver is the same message that you want to deliver. And that is, these drugs can be prescribed and dispensed responsibly or not, and we want them to be dispensed and prescribed responsibly.

We can deliver the message. And we said to Mr. McCloskey, let us work together to develop a message, to develop a program for these doctors. And we did. We developed a brochure, together with Mr. McCloskey. Immediately, at that meeting, we said, let us start to work our people and your people and develop a method of communicating with doctors in this community, which is ravaged by abuse of our product, to try to solve it. And that meeting, and those discussions, resulted in very effective tools, which have been praised by law enforcement throughout the country.

Now, Mr. McCloskey told us that, at that meeting, he realized that there were certain resources that law enforcement has and there are certain resources that law enforcement does not have. And he realized, then and there, something that you have heard throughout this hearing—and I think it is a very significant

thing—and that is, we have to all work together. We are willing. We are eager. We want to do our part.

Mr. McCloskey said that he realized, at the meeting with us, that Purdue had resources and skills that law enforcement didn't have. And the objective is to pull these together and fight the problem. We are here. We have traveled all over the country. Mr. Friedman and I have personally visited—these are not phone calls—we have personally visited with law enforcement people across the country where this is a problem, and we have asked one question. Describe your problem to me and tell us how we can help to solve the problem. We are very sincere on this, Mr. Bass.

Mr. BASS. Is Dr. Haddox here or is he—

Mr. UDELL. No. He is not.

Mr. BASS. He is quoted as saying—and this is the other issue—that Purdue has been working to reformulate OxyContin.

Mr. UDELL. Yes. I think that—

Mr. BASS. And then we have another indication that in the past, prior to that, the company had stated that reformulation was not an option. What has changed? Is this an—

Mr. UDELL. I think that Dr. Goldenheim is really the best one to explain that to you.

Mr. BASS. Fine. Can we have Dr. Goldenheim?

Mr. UDELL. Thank you, sir.

Dr. GOLDENHEIM. Thank you. Could I just say, by way of a preface, that I—as a physician, I am personally very distressed by the abuse of our product. It is clearly causing devastation. It is clearly also helping an enormous number of people. Mr. Chairman, you have made that clear. Other people on the panel have made that clear. As a physician, it is very distressing that our product, when improperly used, is causing such devastation. And, in addition to the methods and actions that Mr. Friedman and Mr. Udell describe, we are aggressively pursuing reformulation.

And, if I might very briefly, in 1996, we became aware that Hydrocodone—you have heard about that drug earlier today, the active narcotic ingredient in Vicodin—was, I think, at the time, the most commonly abused narcotic in the United States. And we embarked on a program to reformulate that drug because, at the time, we were not aware of abuse of OxyContin.

We started to formulate that drug with an antagonist, with a blocker, called Naloxone. Because it was a complicated problem, we wanted to get advice from FDA. And we set up a meeting with FDA, DEA, and the National Institute of Drug Abuse, and that meeting took place in 1997. At that meeting, we were informed that the abuse of Vicodin was via the oral route, and you have heard a great deal about that today, how, in the recent cases with OxyContin, much of the abuse is to crushing the tablet and ingesting it.

We were told that Vicodin was abused orally. As a result, we were told and advised not to use Naloxone. The reason very simply is that Naloxone will not prevent abuse of a narcotic orally. It will prevent the abuse when it is crushed and injected. So, as a result of that, we switched to a different drug called Naltrexone. The advantage of Naltrexone is that it is absorbed orally. But now we have a very difficult problem. Because at one in the same time we

have to make sure that enough is absorbed so that it blocks the high, if you will, so that it blocks the abuse potential, yet, at the same time, doesn't interfere with the pain relief. So we have got a balancing act.

And this was a much more difficult task, a much more difficult hurdle, that was—that we set out for ourselves. And we have been working on that very diligently ever since. Because if we could succeed in doing this, we could have the formulation that would be resistant to oral abuse and intravenous abuse and probably also snorting as well.

In 1998, we had some additional questions, wrote to the DEA. And as recently as 1999, DEA wrote to us and again reminded us that this was principally a problem of oral abuse. It was not until last year, when OxyContin press became so prevalent, when we began investigating, when we had this meetings that were just described to you, that we learned that in addition to the oral abuse, that OxyContin was also, on occasion, being crushed and used intravenously. As a result of that, we have started on a very intensive program, around the first of this year, to formulate it with Naloxone. Again, the Naloxone then will help prevent the intravenous abuse, but won't do anything to prevent the oral abuse.

We have worked very closely with FDA on developing a plan to meet today's standards for what would be required for such a formulation, and we hope, working closely with FDA, to be able to make a submission on a product with Naloxone some time next year. So we are working on it very, very intensively. The Naltrexone, the sort of broader solution, if you will, is more complex and will take several years.

Mr. BASS. Thank you very much, doctor. Thank you, Mr. Chairman.

Mr. GREENWOOD. Before Mr. Bass leaves, I would ask unanimous consent to leave the record open for 10 business days for additional opening statements and supplemental materials. Without objection, it is so ordered. Mr. Bass does have to catch a 4 o'clock train—or plane to Philadelphia. So we are going to excuse him and thank you—

Mr. BASS. Thank you, Mr. Chairman. And thank you all for appearing today. You have been very helpful.

Mr. GREENWOOD. The Chair recognizes himself for inquiry. And let me turn to you, Dr. Levy, if I might. You heard the testimony of Ms. Atwood, sitting next to you, about her—about a member of her family who had the back pain resulting from an automobile accident, was prescribed OxyContin, and then you heard her testify about the way in which he rapidly escalated the dosage until the issue was no longer alleviating his back pain. I don't think he was raising the dosage because the 20 milligrams wasn't working to relieve his pain anymore. He was doing this because of his addiction to the substance, and I assume, because of his desire for the rush, if you will, as opposed to just trying to get the same amount of relief of his pain.

So could you talk to us about that? Tell us what—how does this drug work in that regard? I am somewhat familiar with the fact that addictive drugs, like heroin, stop the production of normal dopamines, I think the term may be, in the brain and, therefore,

the addict starts to increase the dosage just to maintain a level, an even keel. What is the addictive—what are the addictive properties of this drug and how would you account for her—Ms. Atwood's family member's experience?

Mr. LEVY. I guess I would say that first we need to have a common definition of addiction, which is the compulsive use of a substance despite self-harm. We have many patients who have full function on long-term doses of OxyContin, no euphoria, no addiction, but their body can't be fixed from whatever happened to them, whether it is the cancer, the cancer therapy, or an incidental thing that occurred to them prior to or after that.

Mr. GREENWOOD. Well, let me interrupt you there. Does it—when you are in a pain maintenance regime, does it tend to be, generally speaking, that you can use, keep a relatively constant dosage and maintain the palliative effect, but then, perhaps, as the pain increases from a worsening cancerous condition, you increase the dosage? Is that—you don't need a continuously increasing dosage to get the same palliative effect?

Mr. LEVY. That is correct. When we are treating patients who have opioid-responsive pain—and I think that is the key to this—so that we keep them on the same doses for months and years. And we have to be careful not to call them addicts any more than we call our diabetes addicted to their Insulin.

What we are seeming to understand about tolerance, that is, the need for more and more dose, that whereas that more and more dose in our cancer patients is usually because there is more and more cancer. There is another receptor, sort of key and lock in the spinal cord, that has been studied called the NMDA receptor. And that in many chronic pains, either from chronic use of opioids, or from the pain emanating from nerve damage, these receptors start to increase in their population and those pains don't respond well to just opioids.

And if you keep increasing the opioids, you get to the point that you are no longer treating the physical pain. You are starting to treat the psychologic and emotional pain, that many patients will then—the pain doesn't get any better, but they just can take a nap. And there is the patient who starts to get in trouble. Because when you are going to those higher levels, that is when you are going to need more and more Oxycodone.

What we need is better pain assessment and use of those co-analgesics that I mentioned, a variety of medicines that were first discovered to help people with depression or seizures or heart rhythm problems or the installation of pumps and tubes into the spinal cord, that can really help those kinds of pains that all the Morphine or Oxycodone in the world won't help.

So I think the real answer to that is people need to know when they need to refer a patient to a comprehensive center that can look at all of the modalities, physical, invasive, noninvasive, nonopioid, psychological, behavioral. That is the best way to prevent the dose of any opioid from going up and then causing the psychologic imbalance that then gets people in trouble.

Mr. GREENWOOD. Well, then help me out here. I can envision the regime where your patients with cancer come into your center. You monitor their progress. You see them regularly. And, as you indi-

cated in your opening statement, not all of your patients have cancer. You have other kinds of patients suffering from other kinds of pains. And you are monitoring that. You are watching that. And I can understand that. And it seems like it is less likely you have an abusive situation there.

Another situation that I envision, and I think it comes from some of the reading I have done, is somewhere in West Virginia somebody was a coal miner and he hurt his back 5 years ago, 10 years ago. He always had pain and he has tried various things. And his doctor meets a marketing rep from Purdue Pharma who says you ought to try OxyContin for some of these people who have chronic pain. He prescribes the OxyContin. And there maybe—there doesn't necessarily—isn't this constant interaction between physician and patient. There is a renewing of the prescription, maybe an escalation in the dosage, and the next thing you know, you have someone who is in the shape that Ms. Atwood's relative was.

What should the public policy be or what should the medical policy be? And what should—what is the drug company's responsibility there to try to make sure that lots of the first case happens and less of the second case? Let me throw another question in there. And that is the question that Mr. Bass asked the company—should this product be marketed to pain specialists and oncologists and people who are doing what you do exclusively, or should it, in fact, be marketed to a small-town physician who doesn't know much about this kind of regime and just writes the prescriptions as they are demanded by the patient?

Mr. LEVY. When I was a medical student, I participated in putting some patients on a study of a potentially toxic medicine for end-stage heart failure. That was in 1976, and that medicine was Capoten, which that group of ace inhibitors is now the standard for every physician to write for the common starting drug of hypertension. So I think there is an evolution of practice that the specialist in any field develop a new drug, but we clearly can't have every person with high blood pressure have to go to a hypertensive specialist or a cardiologist to get that kind of medicine.

So I think we need to have eyes open and all be responsible. I think that we spent the last 20 years teaching physicians and nurses and pharmacists to listen to their patients, ask them about pain, teaching the patients how to report their pain, and much of that was funded by many of the pharmaceutical companies that are making those Class II medicines.

I think there is another opportunity for the next level of education. And some of the brochures that I have seen from Purdue Pharma are now alerting these doctors to the signs of the side effects, the signs of abuse, the signs of inappropriate use. Much like when Tagamet came out, it was the best thing since sliced bread, then caused a lot of side effects, and then there was appropriate new information. These cycles in medicines can be up to 3 to 10 years.

I think what we need to do is to increase the education of all clinicians on appropriate pain assessment. There are—a lot of them—clinical education, as sort of looking as pain as a disease. Our whole medical model was that pain was a symptom of other diseases and that you just simply treat them and the pain will go

away. And our experience over the decades is we can't always do that.

I think there also is the Federal—there are Federal guidelines for State Medical Examiner Boards that talk about—that I am sure would say that, just what you mentioned, casually seeing—you know, giving a new script for the patient, but not re-evaluating them every couple of months, would be bad medicine. I mean, because we are looking for comfort and function. And when I see a patient who needs a rapid increase in their medicine, I am thinking, what did I miss? And we need all clinicians to think, what is the mechanism of this pain? What can we do specifically to deal with the pain, its transmission, and to minimize the dose of a non-specific opioids to try to optimize comfort and function? And that is an education event that could use more and more Federal funding, as well as drug company funding.

Mr. GREENWOOD. Let me turn to Dr. Jenkins, who has been sitting patiently for all of these hours, from the Food and Drug Administration. And while the Food and Drug Administration has not offered to make an opening statement or offer testimony, Dr. Jenkins is kind to come to answer any questions.

What policy implications might we draw here? I know that there has been some discussion about whether or not these—this drug can be reformulated to thwart its vulnerability to abuse. This is a science that has been around prior to the launch of OxyContin. And the question that occurs to me, as a legislator, as a policymaker, is should a Class II drug like this, or similar drugs that have this potential for abuse and for addiction, should this whole question of inhibitors be part of the approval process from day one, as opposed to launching a very powerful drug like this and then coming back and trying to close the barn doors after the horses have left?

Mr. JENKINS. Thank you, Mr. Chairman. First of all, we do not require that the antagonist be added to opioids, at this time, for approval. When OxyContin was approved by the FDA in 1995, it was done with the history of knowing that there were other sustained-release narcotics already approved. We have heard about MS-Contin. There was another compound called Duramorph. These were Morphine products that were sustained-released products. We had not seen evidence that those were subject to widespread abuse and diversion. So at the time that OxyContin was approved, it had been shown to be safe and effective in clinical trials for treatment of moderate to severe pain, and there was no reason, at that time, to suspect the type of abuse that we have seen subsequently, and there was no reason to consider requiring the addition of an antagonist.

There are issues that have to be addressed when you think about adding an antagonist to a formulation. There are sometimes very complicated chemical issues, formulation issues. There are complex pharmacology issues. There is also the fundamental question that you have to address, that most of the patients who are receiving the combination product, don't need the antagonist. So they are receiving a drug and being exposed to a drug that may have its own side effects that they don't need.

So as a policy, we have not required that opiates contain antagonists at the time of approval. That is currently our policy. We have

been willing to work with companies in situations where widespread abuse and diversion have become an issue, to address whether adding an antagonist will help to address the problem.

I think it is important, though, that adding Naloxone to OxyContin is not going to totally solve this problem. There will be potential ways that addicts will find to get around that addition. And there are also questions that have to be addressed to make sure that legitimate patients still get the pain relief that they need from the drug and that they are not blocked by the antagonist. So it is a very complicated issue.

Mr. GREENWOOD. Well, you made reference, Dr. Jenkins, to the statutory requirement that the Food and Drug Administration must determine that a drug is both safe and effective before it approves it for market. And the question that is occurring to me—and I was involved in rewriting the Food and Drug Administration Act several years ago—is whether for drugs of this nature, that have such a potential to be abused, as well as, as we must all continue to reiterate, the magnificent potential it has to relieve pain, whether there ought to be an additional standard that apply—and that is, that these drugs be safe when used according to prescription. That they be effective when used according to prescription and that all practical steps are taken to reduce the likelihood of their abuse.

And it seems to me that a product of this power, a powerful drug like this, should, in the future, that perhaps the Congress ought to take into consideration adding an additional standard. And that is to make sure that the manufacturer and the agency think through, in advance, what are the things that need to be done in terms of marketing restrictions, if necessary, in terms of antagonists, that may or may not be appropriate, in terms of education, in terms of thinking through who should the prescribers be, and who might the prescribers not be. Maybe we need to add that step to this process, because I don't think it exists. And, correct me if I am wrong, I don't think it really—there is such a rigorous process in the ordinary FDA approval process.

Mr. JENKINS. Actually, Mr. Chairman, there is. We have a controlled substances staff in the Center for Drug Evaluation and Research, and their responsibility is to evaluate products that are going to be scheduled and evaluated abuse liability and communicate with the reviewing divisions about steps that can—

Mr. GREENWOOD. And that happened in the case of OxyContin?

Mr. JENKINS. I am sure it did. Remembering that Oxycodone, the base substance in OxyContin, was already a Schedule II narcotic in 1995, when OxyContin was approved. So it was already going to be a Schedule II product. Now, we have learned from the recent events and we will certainly be applying those learnings of what we have seen with the abuse liability for sustained-release products like this one to OxyContin and our dealings with the company now and also to future products.

So—but abuse liability is part of what the FDA does when we are assessing products as they are being developed. We often see products and we have great concerns about the ability of those products to be abused and we recommend the changes in the formulation or packaging, or, even in very rare cases, the distribution and prescribing patterns for the drug, to try to limit that abuse.

Mr. GREENWOOD. Ms. Atwood, let me turn to you. You described poignantly your family member's experience, having been injured in a car accident, taking the drug, and then quickly accelerated the dosage and becoming essentially captive to its power. You also treat other people who have used and abused OxyContin. Can you talk a little bit about the profile of those folks? For instance, do you see—have you seen in your practice other instances of individuals who began this process with a legitimate prescription and followed a course similar to the one you described, as well—and to what extent to you see that versus people who aren't experiencing pain, don't have a legal prescription, but have become addicted to the drug by acquiring it on the street?

Ms. ATWOOD. Let me start—I kind of want to jump back to what you asked Dr. Levy. I think that a lot of times the increase in dopamine that you were talking about, in addition to the increase in intercellular or extracellular dopamine, there is also an increase of indigenous opioids that happen. So this is a really powerful thing. And I think that it is very sad that to this point you haven't heard about the physiology of the addiction. We know how it happens in pain, but we are not—it wasn't discussed how it happens in addiction. And I think that that is very sad.

Mr. GREENWOOD. I am all ears, if you want to get at it.

Ms. ATWOOD. Well, I just—I think that the same concern that a doctor would take if a patient came in with COPD. And knowing the side effect of the respiratory side—the respiratory depressant side effect of that, a doctor seeing a patient that had COPD would be very cautious—

Mr. GREENWOOD. What is COPD? COPD is—

Ms. ATWOOD. Chronic obstructive pulmonary disease.

Mr. GREENWOOD. Okay.

Ms. ATWOOD. A doctor would be very cautious in prescribing an opiate because the opiate receptor has three parts to it, the euphoria, the analgesic, and the respiratory depressant. So if you know you have all three, you would be very cautious in prescribing a respiratory depressant to somebody that already has a respiratory depressant problem.

And what occurred to me when you talking to these gentleman about the Naltrexone and the—those two antagonists—

Mr. GREENWOOD. Antagonists.

Ms. ATWOOD. [continuing] that maybe if doctors had the time—I know sometimes doctors purposely don't do that, but I don't often think that is the case, and I think that an entire examination of the health care system as it stands today also would be necessary in this discussion. But in any case, I think that if we knew that this person was walking in there with a history of the disease of addiction that then maybe there could be a form of the drug just for them so that we weren't medicating people that weren't addicts with the antagonists and we were giving addicts that had pain and needed this drug with the antagonist.

Mr. GREENWOOD. And are you seeing—to the question of the street utilization, you are seeing people who have not had any prescription whatsoever, not had any history of pain, and who acquired this drug on the street as a so-called recreational drug and became addicted or just be—what have you seen in that regard?

Ms. ATWOOD. I would say that most times they have already had a chemical dependency predisposition. I have seen—in addition to my relative, I have seen 2 or 3 other kids that came in and were on it for car-related car accident trauma that became addicted. Otherwise, yes, it started out with recreational use. And I think that speaks to our society and culture.

Mr. GREENWOOD. I am going to ask this panel, as I did the last panel, if there are any comments or statements or lines of dialog that you would like to entertain that you think that we haven't elicited with questions yet.

Mr. UDELL. If I may, Mr. Chairman?

Mr. GREENWOOD. Yes, certainly.

Mr. UDELL. At the very beginning of the hearing, Mr. Chairman, I think you quite correctly pointed out that we are facing the problem of prescription drug abuse in the United States, that it is a serious problem. And I think that thread that should run through this hearing is that we shouldn't focus entirely on OxyContin, but we have to focus on the entire problem of prescription drug abuse. It is quite understandable that much of the time today has focused on OxyContin because today, here, that seems to be the principal problem.

However, what we have seen, even in the experience of OxyContin, we have seen this cycle in and cycle out. And the example that I will give you of that—that explains that, sir, is that at the very beginning of the problem, just after Washington County, Maine, where we first observed this problem, ground zero was Lee County, Virginia. Bucks County may be ground zero today, but, at that time, it was Lee County, Virginia. And Michael Friedman and I traveled to Bucks County—

Mr. FRIEDMAN. To Lee—

Mr. UDELL. [continuing] to Lee County, Virginia, and we met with the sheriff and the Commonwealth attorney. And I said to Sheriff Parsons, after I heard the devastation that he described—I said to him, sheriff, if OxyContin disappeared from Lee County, Virginia, tomorrow, what would things be like? And he said to me, Mr. Udell, the people who are abusing OxyContin today would go back to abusing the drugs that they abused before OxyContin. And what he said has proven to be the case, because I spoke with him again just last week and I said to him, sheriff, how are things on the streets in Lee County today?

And he said to me, we no longer have an OxyContin problem in Lee County. He said, we have arrested the principal doctor who was responsible for illegal distribution of it, as has been the case in Bucks County. And he said the efforts of law enforcement, the cooperation of Purdue Pharma, which provided him with placebo tablets, so that he was able to do reverse buy-and-bust sting operations—the combined efforts of law enforcement, the company, the medical education programs that we have done—that we have conducted in that area, has eliminated the problem. There is no OxyContin problem on the streets in Lee County he told me last week.

And I said to him, and what is the condition of drug abuse in Lee County? And he said, I am very sorry to say that the people

who were abusing OxyContin are now abusing the other drugs—Vicodin, Percocet, Lortab, and so on. And so I think is—

Mr. GREENWOOD. With equally fatal results?

Mr. UDELL. You know, I have not seen recent autopsy data. But I can say, sir, that the entire problem of prescription drug abuse is accelerating. And if you look at the chart, which is no longer there—if you look at the chart, what we did see was that when OxyContin was introduced, up until just last year, up until the year 2000, the deaths from Oxycodone-containing products were the same as they were before. The last year before OxyContin was introduced, I saw five deaths in that county—five deaths. And up until the year 2000, the number was five deaths. So I would submit, sir, that even before there was an OxyContin, people were abusing prescription drugs and dying from it.

And that brings me to the second point I would like to make. Again and again we heard about education. We have got to teach these kids that abusing a prescription drug is as significant and as serious as abusing heroin. And we believe that, as a company that makes a prescription drug, we have an obligation to be a part of that process. And we have done so, on our own. We have instituted public service announcements directed at teenagers in areas where there is abuse, telling them just that.

Mr. GREENWOOD. What is your budget for that?

Mr. UDELL. I don't know what we have spent. But I can tell you something else we have done, sir. We commissioned an organization that specializes in marketing products to teenagers and to preteens. And we said to them, assume that the product that you want to sell is don't use prescription drugs. Come up with a program directed at these teenagers and preteens telling them that it is as dangerous to use a prescription drug as it is to use heroin. We did that. We developed a program. We have carried that program to people who are specialists, to people who are experts in communicating things like this to young people, and they have applauded it and celebrated it. This is something where we stepped up to the plate and we did it.

And we would like very much to make those materials available here in Bucks County because we think that materials like this can help in Bucks County. We have developed them and we would like to make them available here. And I would very much like, sir, if someone could tell us who the contacts should be here in Bucks County so that we can start to use this program to educate kids in this county on the dangers of prescription drug abuse.

The third point, sir, is one that you and I have discussed before, and that is prescription monitoring programs. I don't think that that has been discussed here, but it really is the answer to a lot of the questions that have been asked. When we met the last time, you said to me, what is the one thing that the Federal Government can do to help this problem? What do you think we can do? And my response then is the same response it is now, and I know that you agree with this. And that is prescription monitoring programs.

Prescription monitoring programs have proven again and again to be highly effective in dealing with the problem of diversion of products like this. But there is a role that is unique to the Federal Government. And that is, the Federal Government can solve the

problem that now exists with respect to existing prescription monitoring programs. And that is, they are a patchwork. They are inconsistent. There are some that are horrible. There are some that are pretty good. And we believe, and we have supported from inception, from the moment we learned about this problem—and I believe we are the only pharmaceutical company in the country that supports this—the institution of effective prescription monitoring programs.

And we believe that the Federal Government, that the Congress of the United States, can define standards, can set standards for prescription monitoring programs, encourage the States to implement them. Make them real time so that you don't have to wait weeks or months to get the data. Make them real time just like when you put your credit card in a restaurant, they instantly know whether or not that credit card is good. We have that technology and we should use it to solve this problem. And we are encouraging States to do that and we fully support you, sir, in your efforts to have the Federal Government do that as well.

It is also important that a doctor in State "A" can query the data base in State "B" to find out whether or not his patient is going across the State line and buying prescription drugs and getting prescriptions in another State. Now, right now, the citizens of Pennsylvania—I am sorry—the doctors of Pennsylvania would be unable to query a data base in New Jersey because—if both States had prescription monitoring programs—because the State of New Jersey doesn't recognize the authority of a doctor in the State of Pennsylvania to do so.

And similarly, a law enforcement officer. Mr. Demarest, if he wanted to find out what was happening across the line in New Jersey, and New Jersey had a prescription monitoring program, they wouldn't recognize that either. And that goes back again to this question of cooperation and sharing of information. And I believe there is a very important role for the Federal Government in this area, which we fully support, in trying to pull all of this together, establish standards and say to the States, if you do this, it will help and we will incentivize you to do it.

Mr. GREENWOOD. And, as a matter—I appreciate that. And, as a matter of fact, it is my intention to hold a hearing in the relatively near future on that very issue on how we can find an appropriate Federal role in prescription monitoring programs for the States and how we can add to that.

Let me ask you three quick questions. Is there any thought on the part of your company of moving from the process of paying your sales force on a commission basis on—based on the volume of sales for this product?

Mr. UDELL. The question of our compensation programs has been raised. It was raised early on in the process and we have considered it, we have studied it, and we have made some changes, in part, in response to suggestions by people in government. And we are continuing to look at this.

As we look at it today—I recently looked at a survey—I guess it was last week—our program is consistent with that of every other company selling drugs which are more abused than OxyContin. And I think that this is something that has to be studied by the

industry. Now, you know, we can't combine to do this because of antitrust considerations. But, on the other hand, if we developed a system that was far different from that utilized by other companies, it might be a problem in terms of attracting qualified people to our company. And I think you are correct that these are issues that should be studied by all companies in the industry and we are doing so.

Mr. GREENWOOD. Have you considered or have you, in fact, dedicated some percentage of your profits to rehabilitation of your—those who have become addicted to your product?

Mr. UDELL. The question of rehabilitation is an interesting one because as we have visited with law enforcement and government people, what occurs—what appears to us is that we have got to work at the root causes of these problems. The people who end up in treatment centers, they need the help. They must get the help. But they are the people who have failed this—where the system has failed them earlier on. And we think that we have got to focus on that.

We have got to focus on developing abuse-resistant formulations so that we don't create—so that people don't become addicted to our product. We have got to do the education of young people to make sure that they don't abuse this product because they think it is just another drug and not as serious as heroin. We have got to focus on educating doctors, the way we described earlier, to make sure that they understand how to produce these—how to use these products properly.

Those attack the root causes of the problem. And we are committed to spending substantial sums of money in that area. Research alone is costing us—on abuse-resistant formulations, is costing us tens of millions of dollars each year. That is just research alone. The development of the other programs I have spoken about are also significant.

The fact that Michael Friedman and Howard Udell and Paul Goldenheim are traveling all over the country trying to go to areas where there is a problem and say how can we help? We care. We are serious. We want to help. That has a cost too because we are not available back home to run the business. And we are on the road. Michael Friedman and I have been on the road constantly since last September when we visited with Mr. McCloskey. And that is a cost, as well, sir.

Mr. GREENWOOD. Okay. Mr. Levy, did you have a comment you wanted to make?

Mr. LEVY. Yes. I think, in summary, I would like to urge a note of caution that, you know, simple problems to complex—simple solutions to complex problems rarely work. And that we need to be careful not to demonize Oxycodone or glorify Naloxone. Now, you have spoken many times of the sheer potency of Oxycodone and it, perhaps, is twice as strong as Morphine, but Hydromorphone is four times as strong and Fentanyl is 50 times as strong.

So it isn't just the potency. It is the process of how these medicines are used and how they then get abused. Studies in cancer patients have documented in tens of thousands of patients that we do not create addicts by medical prescribing. And the several studies have been done in this country and in Europe when we look at ad-

dicts in chronic noncancer pain patients, like the patient, you know, with the car accident. The same percent of the normal population that has substance abuse, 6 to 10 percent, is that number in those who are in pain clinics.

So we have to do this professionally. We have to, you know, fix the problem, not the blame. We need to recognize that it isn't that simple scientifically. There is not just three types of things. There are, at least, 10 opioid receptors. And so it is not that easy to jump and find a magic bullet as much as we would like it. Attempts at mixed drugs, like Talwin, which were—and Nubain, which were part agonist, part antagonist, showed that they had a ceiling, they didn't relieve severe pain, and they caused different side effects that made them worse than pure opioids so that the Agency for Healthcare Policy and Research says do not use them.

So we need to have a note of caution. We need, I agree, as everyone else has said, to work together. We need to not allow inference to creep in, such as the comment of having conversion guidelines from Darvocet or Codeine to Oxycodone. That is because those drugs don't work. And if we didn't tell the physicians how to get the patient on the right dose of Morphine or Oxycodone, we had a patient staying in pain.

So I think we need to go down to the consensus that we all have, that we want to help patients, help our society. We unfortunately live in a society that condones abuse. Our society abuses alcohol, tobacco, food, and fast cars. They all are killers. We need to have a rational public policy approach that helps get the right medicine to the right people and the right education to the right people. I don't think that OxyContin is any more lethal than any other medicine. I think because of things that have been discussed, it is accessibility, that kids don't know that what color is what milligrams. And that is why, I think, we have seen more deaths from OxyContin than we have seen—you know, recently than we have seen from Hydromorphone or Fentanyl.

So I think we need to keep it in perspective. We need to look at our whole culture. And I hope we all have an opportunity to work on a process together, with education and monitoring, with appropriate resources so that we can really get both of these epidemics under control.

Mr. GREENWOOD. Thank you. Ms. Atwood, any final comments?

Ms. ATWOOD. I would like to, first of all, thank you very much for inviting me to be here. I think that any discussion that has to do with addiction and drugs of abuse and so forth, I think that the underutilization of the recovery community as a resource and as an assistance in educating and preventing and policing and treatment, that we are very highly effective, as well as cost effective, resource for all of you to use. And I wish that you would let us be available to you.

Mr. GREENWOOD. Thank you. Mr. Jenkins?

Mr. JENKINS. I would just like to thank you for allowing us to be here today. We do take this problem very seriously and we are going to do all we can, from our perspective, to try to address this problem.

Mr. GREENWOOD. Well, thank you, all. This committee has a responsibility to put issues like this under the microscope to ask the

tough questions. And we also have the responsibility though, as legislators, to be part of the solution. And, as I said, we will be looking into the issue of how we can do the monitoring and how we can find Federal policy issues so that we can, in fact, work with the manufacturers, work with the abuse treatment community, work with evaluative community, and the FDA to make sure that in this product and similar products society gets to reap the benefit and minimize the anguish.

Thank you all again. I want to thank, again, Mayor Joe DiGirolamo for generously allowing the Congress to use the public meeting room. I also want to again thank his Executive Assistant, Ms. Barbara Barnes, for coordinating with my staff on this. And, finally, Mr. Ralph Douglas, the Chairman of the Bensalem Cable Advisory Board who has volunteered to spend all of his time here covering this broadcast and taping it for the township. And thank you all once again. Thank you, audience, for participating. And this hearing is adjourned.

[Whereupon, at 3:12 p.m., the subcommittee was adjourned.]
[Additional material submitted for the record follows:]

PREPARED STATEMENT OF EDWARD J. BISCH

I would like to thank the members of the committee for allowing my voice to be heard. My name is Edward Bisch from Philadelphia PA., On Presidents day of this year. February 19, 2001 I received a call that all parents DREAD and pray they NEVER receive. Christi my 15 year old daughter could not wake her brother "Eddie" up. That was the first day I ever heard the word OXYCONTIN. I was shocked when a police officer came in the house and said Oxycontin, "kids are dying left and right from this"? I could NOT believe what I was hearing and angrily yelled? WHY DID I NEVER HEAR OR WAS WARNED ABOUT THIS DRUG?

From that moment on I started to educate myself on Oxycontin and started warning as many people as I could about the devastation of abusing it. My family and I quickly decided to publicly AIR our dirty laundry about Eddie's death to get the word out to as many people as possible about OXYCONTIN ABUSE. We notified the MEDIA and were more appalled when the Philadelphia Daily News reported OXYCONTIN was also involved in 20 Philadelphia deaths within a three month period, but no warning was given about this rising epidemic?

We called a community meeting and my sister called all the media outlets in the City, to help us get the word to the Philadelphia region about the DEADLY abuse of this drug. The media responded that night and all the TV, Newspaper and News radio stations reported on the Previously unpublicized killer.

I myself personally started a CHAIN email to also help warn people here and throughout the country. The email then evolved into a website (oxyABUSEkills.com) and now the website has evolved into a Nonprofit organization called the PDAAP (Prescription Drug Abuse Awareness & Prevention). All this is in loving Memory of my son Eddie Bisch.

Needless to say this has devastated my family and particularly Eddie's Mom who has had several breakdowns trying to deal with this terrible and shocking tragedy.

I commend this board for helping US bring awareness to this still rising problem.

Since Eddie's death most of my free time has been spent either researching or working to spread the word about OXY abuse. I have also talked to hundreds of people all over the country through my website from Government Agents, politicians, doctors, abusers, reporters, informers, grieving relatives of other victims, drug companies, cancer patients. and Chronic pain patients. Oxyabusekills.com has had over 30,000 visitors. I also volunteer and talk at schools and community groups about OXY abuse. If there is such a thing, I would consider myself an UNWILLING expert on OXY ABUSE.

I have learned that this is a complicated and history making situation due to the fact that people in Severe Chronic Pain really do need this drug and I am totally against BANNING it but I personally feel it should ONLY be used for SEVERE PAIN because it is a very powerful pain killer and it is too easy to FAKE moderate pain which contributes to the diversion problem. Now that this ABUSE EPIDEMIC is being acknowledged the question is how do we slow or stop this ABUSE epidemic?

Winning this battle is not going to be easy, it will take the combined efforts of the public, government, doctors, patients and Manufacturer (PurduePharma) which has already started some education programs.

I'd like to publicly suggest the following:

- 1) We need to identify and Prosecute doctor shoppers and publicize this to let others know the FREE RIDE is over. For too long Police have looked the other way or have not allocated enough resources to stop this crime. Computerized monitoring is the best way to do this BUT we need to get this speedily implemented and all 50 states need it.
- 2) It should NOT take 9 months to Arrest Crooked Doctors or Pharmacists who have been identified. Dr. Paolino of Bensalem PA. was able to put around 300,000 pills on the street while under investigation? This delay should be investigated and If this is the NORMAL system then something needs to be changed to speed it up.
- 3) Training should be readily available and REQUIRED for any doctor who writes prescriptions for oxycontin. There are not enough Pain Management Specialist to limit the prescribing to them but a shorter course should be REQUIRED for any doctor who writes a prescription for this powerful pain killer.
- 4) Doctors should be legally required to explain tolerance/dependence to people. I have received MANY emails from legitimate patients who were not explained anything except take twice daily, Many of these legitimate patients eventually became abusers.
- 5) Legitimate patients who resell part of their prescription need to be made aware that this is DRUG DEALING, people are DYING and this NO LONGER will be overlooked. This is another crime law enforcement has overlooked for too long.
- 6) Treatment needs to be readily available so a person who wants help can have it immediately. the deaths are getting the headlines but there are MANY more already addicted. If treatment is not available then when the OXY supply does start to dry up, MANY OXY abusers will turn to heroin.
- 7) Finally, Continue to educate everyone, especially teens on the dangers of Abusing Prescription Drugs.

As you have heard in previous testimony that Most OXY related deaths also involved other drugs including alcohol and Eddie was part of this majority as early the day before he died, he had abused another prescription drug XANAX.

I realize it was Prescription Drug Abuse that killed Eddie, but OXY is the straw that is breaking the camel's back in most of these death's, not to mention how many more are now addicted to it. Government agencies have documented that PILL POPPING is rapidly rising among teenagers. This is why we have founded the PDAAP, to develop programs to educate the teens on how DANGEROUS/ADDICTIVE it is to Abuse pills. I somehow would like to be a partner/volunteer to this committee to help educate the children, to at least give them a fighting chance. To properly warn them of the consequences when they choose to abuse pills. This is the 21st century with 21st century drugs and we NEED 21st century drug education programs.

Thank you and I will help in anyway I can and ANYONE at anytime can contact me through my website oxyABUSEkills.com. WARN ABOUT OXY ABUSE to ENSURE ACCESS FOR PROPER USE.



Purdue Pharma L.P.

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September 5, 2001

Hon. Jim Greenwood
Chairman
Subcommittee on Oversight and Investigations
2436 Rayburn House Office Building
Washington, DC 20515-3808

Dear Congressman Greenwood:

Under the ten day general leave to revise and extend my remarks, I am enclosing a Supplement to my testimony before the Subcommittee on August 28, 2001. Please include this as a part of the permanent record of the Hearing.

Very truly yours,

A handwritten signature in cursive script that reads "Howard R. Udell".

Howard R. Udell
Executive Vice President
General Counsel

HRU:pt
Enc.

SUPPLEMENT TO THE STATEMENT OF PURDUE PHARMA L.P.

**BEFORE THE
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS
HOUSE ENERGY AND COMMERCE COMMITTEE**

AUGUST 28, 2001

Mr. Chairman:

In response to a question from the Committee, Mr. Udell discussed the state of the problem of abuse of OxyContin[®] Tablets in Lee County, Virginia. Attached as Exhibit 1 is an Affidavit of Gary B. Parsons, Sheriff of Lee County, Virginia submitted in a Kentucky law suit involving Purdue. Sheriff Parsons states: "In recent weeks, I have observed what appears to be a significant reduction in the abuse of OxyContin. I have seen a re-emergence of previous drugs of abuse such as Lortab, Tylox, and Xanax. The street value of OxyContin tablets has increased and contributed to this reduction in use. I also attribute this reduction in the abuse of OxyContin to the efforts of law enforcement, the arrest of corrupt doctors, heightened awareness of prescription drug abuse to educational efforts, and the assistance of Purdue Pharma, L.P. in supplying our office with placebo OxyContin tablets to be used in reverse buy and bust operations." As appears from Sheriff Parson's Affidavit, while the problem has not yet been fully resolved in Lee County, it has been significantly reduced and previous drugs of abuse have re-emerged.

Purdue also wishes to reinforce the comments made regarding the sudden emergence of the problem of OxyContin abuse and the fact that it caught all of us, including Purdue Pharma by surprise.

Attached as Exhibit 2 is a copy of an OpEd piece published in the Lexington, Kentucky *Herald-Leader* on September 3, 2001 by Joseph L. Famularo, who was formerly U.S. Attorney for the Eastern District of Kentucky and is now serving as a Kentucky Commonwealth Attorney and consultant to Purdue Pharma. Mr. Famularo states:

“It [Purdue Pharma] did not have any reason in 1995 to expect or anticipate the abuse of OxyContin. The sudden rise in the drug’s abuse, some four years after it came to the prescription drug market, took everyone by surprise, including the Food and Drug Administration, law enforcement and Purdue.

I first heard of the OxyContin problem in southeastern Kentucky in the early fall of 2000, while I was a U.S. Attorney. Likewise, the Drug Enforcement Administration supervisor for Kentucky told me that he had not heard of OxyContin until he was assigned to Kentucky in late 2000.”

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF KENTUCKY
LONDON DIVISION

Case No. 01-268

AMY FOSTER, et al.

PLAINTIFFS

vs.

PURDUE PHARMA, L.P. et al.

DEFENDANTS

AFFIDAVIT

Comes the affiant, GARY B. PARSONS, and after being first duly sworn, states as follows:

1. I am the Sheriff of Lee County, Virginia, and have served in such capacity for five years.

In connection with my responsibilities as Sheriff, I have had the opportunity to observe the abuse and diversion of various elicit and illicit drugs in Lee County.

2. In recent weeks, I have observed what appears to be a significant reduction in the abuse of OxyContin. I have seen a re-emergence of previous drugs of abuse such as Lortab, Tylox, and Xanax. The street value of OxyContin tablets has increased and contributed to this reduction in use. I also attribute this reduction in the abuse of OxyContin to the efforts of law enforcement, the arrest of corrupt doctors, heightened awareness of prescription drug abuse to educational efforts, and the assistance of Purdue Pharma, L.P. in supplying our office with placebo OxyContin tablets to be used in reverse buy and bust operations.

Further the affiant saith not.


GARY B. PARSONS

Subscribed and sworn to before me by GARY B. PARSONS this 29th day of August, 2001.

My Commission Expires: 4/30/2002


NOTARY PUBLIC,

(SEAL)

Respectfully submitted.

STILES & HARBISON, PLLC



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ATTORNEYS FOR DEFENDANTS
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PURDUE PHARMA INC., AND
THE PURDUE FREDERICK
COMPANY

CERTIFICATE OF SERVICE

This is to certify that a true and correct copy of the following was served by hand-delivery or first class U.S. mail, postage prepaid, this 29th day of August, 2001, upon:

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THE PURDUE FREDERICK COMPANY

Published Monday, September 3, 2001, in the Herald-Leader

OxyContin abuse not maker's fault

By Joseph L. Famularo

The editorial on OxyContin abuse said it was too bad Purdue Pharma, the manufacturer of OxyContin, didn't develop an abuse-resistant version before putting the painkiller on the market in 1995.

This is unfair to Purdue Pharma. It did not have any reason in 1995 to expect or anticipate the abuse of OxyContin. The sudden rise in the drug's abuse, some four years after it came to the prescription drug market, took everyone by surprise, including the Food and Drug Administration, law enforcement and Purdue.

I first heard of the OxyContin problem in southeastern Kentucky in the early fall of 2000, while I was a U.S. attorney. Likewise, the Drug Enforcement Administration supervisor for Kentucky told me that he had not heard of OxyContin until he was assigned to Kentucky in late 2000.

Since the OxyContin roundup in February, which was the largest drug bust in Kentucky's history, Purdue has reached out to law enforcement in a joint effort to reduce the illegal use of OxyContin. Purdue helped sponsor and present a full-day seminar in Hazard in March.

I spoke at the seminar, which was attended by more than 200 health-care professionals. It included information about recognizing patients who scam medical doctors into writing prescriptions as well as other topics related to helping the health-care profession deal with the problem.

OxyContin abuse is a major problem in Kentucky, particularly southeastern Kentucky. But, OxyContin is not the demon; its misuse is. Doctors prescribe OxyContin to thousands of legitimate patients who are effectively using this painkiller to alleviate suffering.

In 1995, Purdue could not have anticipated that the abusers would crush the pills, bypassing the drug's time-released effect, and get a full dose at once by injecting or inhaling it.

To suggest otherwise is unwarranted.

